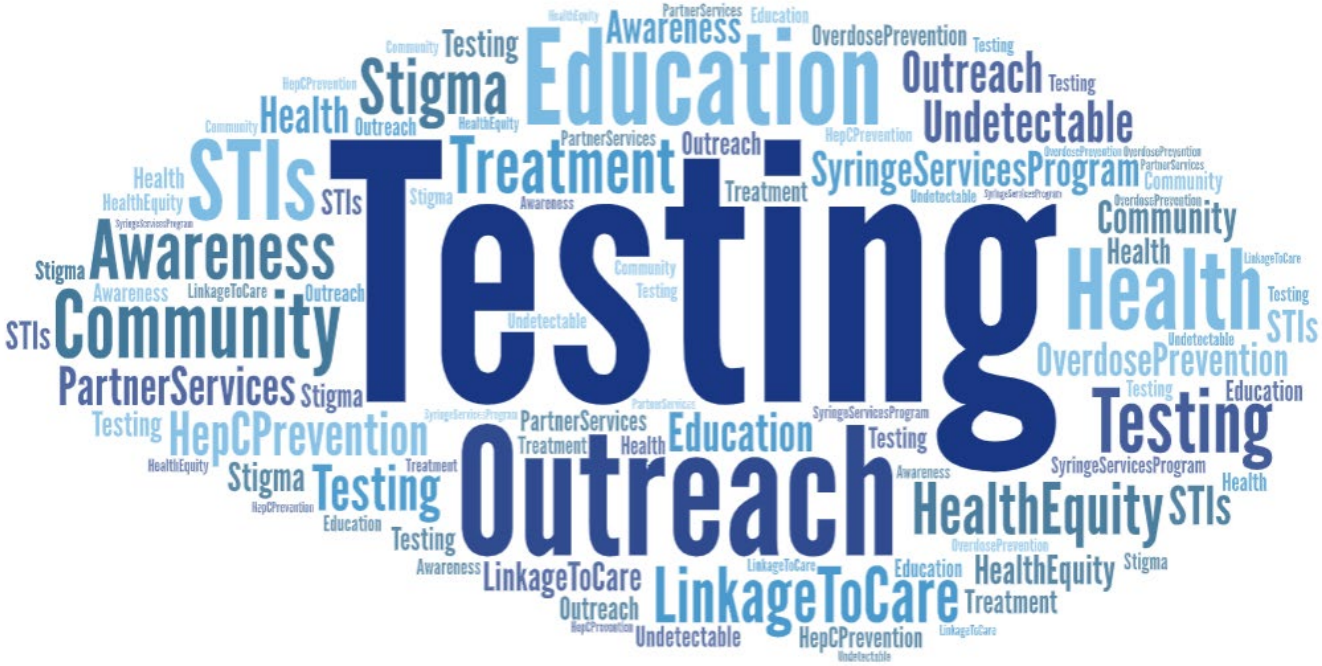
Implementing HIV Testing in Nonclinical Settings

Policies & Procedures Manual for CT DPH Funded HIV Testing Providers



Revised February 1, 2022

Program guidance intended for use by CDC-funded HIV testing providers in nonclinical settings.
HIV testing providers not funded by CDC may also find this information useful.

HIV Prevention & Care Programs
TB, HIV, STD & Viral Hepatitis Programs
DPH Connecticut Department of Public Health
PHAB

Acknowledgments

The *Implementing HIV Testing in Non-Clinical Settings: A Guide for CT HIV Testing Providers* (herein after referred to as Implementation Guide) was created to support the implementation of HIV testing services in nonclinical settings throughout the state of Connecticut. The Implementation Guide was developed by the Connecticut Department of Public Health (CT DPH), Public Health Initiatives Branch TB, HIV, STD & Viral Hepatitis Programs, HIV Prevention Program. This Implementation Guide is a collaboration of previous versions created by both the CT DPH and CDC. Many persons supported the creation of this Implementation Guide and contributed to its development.

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Introduction

This protocol describes prevention interventions funded by the State of Connecticut Department of Public Health (CTDPH), TB, HIV, STD, & Viral Hepatitis Program, HIV Prevention Program The content of this manual is based on guidelines from the Centers for Disease Control and Prevention (CDC) and was modified by the CTDPH to address prevention service standards, requirements, and prevention programming in Connecticut. This document is consistent with the Requests for Proposals (RFPs) that fund Outreach, Testing, & Linkage (OTL), and Effective Behavioral Interventions.

Purpose

The purpose of the protocol is to assist agencies in designing and implementing effective programs, to ensure that clients receive high-quality and appropriate services and to enable the CTDPH, HIV Prevention Program to monitor contracts in a consistent manner. Additionally, the protocol guidance and definitions are provided so that all funded program sites and Contract Managers will be able to describe, discuss, and evaluate their work using a common language. Adherence to the protocol will be assessed in each funded sites' performance.

Effective HIV Prevention Policies

Effective HIV prevention services are based on the following policies:

- Client confidentiality must be strictly protected.
- Informed consent must be obtained prior to services such as HIV and HCV testing. Written informed consent is required for HIV testing in non-clinical settings.
- Confidential testing is the preferred method of testing by DPH funded sites.
- Information about the HIV test must be provided to all who request or accept HIV testing,
- HIV prevention services must be provided in a manner consistent with applicable local, state, and federal guidelines, policies, and statutes.
- HIV prevention services must be provided in a manner that is responsive to community needs and priorities (e.g. is available and accessible).
- HIV prevention services must be appropriate to clients' culture, language, sex, sexual orientation, age, and developmental level.
- Providers of HIV prevention services must develop and implement written protocols for OTL services.
- Providers of HIV prevention services must develop and implement written quality improvement and evaluation protocol and procedures.

Goals and Objectives

The CTDPH HIV Prevention Services Goals & Objectives are in alignment with the National HIV AIDS Strategy (NHAS) and the Centers for Disease Control and Prevention (CDC).

Goals:

- To reduce the number of new HIV infections in Connecticut.
- To reduce HIV risk behaviors in focus populations identified by the Connecticut epidemiological data.
- To ensure access to HIV prevention services such as: education, counseling and testing, partner notification, medical case management, and referral services.
- To improve integration of services across health and human service programs serving focus populations.
- To incorporate evaluation and behavioral science into HIV program planning, development, and implementation.

Objectives:

- Ensure that people living with HIV and persons at increased risk for contracting HIV
- Have access to HIV testing to promote early knowledge of their HIV status.
- Receive high-quality HIV prevention counseling to reduce their risk for transmitting or acquiring HIV.
- Have access to appropriate medical, preventive, and psychosocial support services.
- Receive information regarding HIV transmission, prevention, and the meaning of HIV test results upon testing.

Acronyms

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARTAS	Antiretroviral Treatment and Access to Services
CADAP	Connecticut AIDS Drug Assistance Program
CBA	Capacity Building Assistance
CBO	Community-Based Organization
CDC	U.S. Centers for Disease Control and Prevention
CHPC	Connecticut HIV Planning Consortium
CLIA	Clinical Laboratory Improvement Amendments
CPP	Comprehensive Prevention for Positives
CT DPH	Connecticut Department of Public Health
D2C	Data to Care
DIS	Disease Intervention Specialist
EBI	Evidence-Based Intervention
FDA	Food and Drug Administration
HAART	Highly Active Antiretroviral Therapy
HCO	Health Care Organization
HCV	Hepatitis C Virus
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HNS	HIV Navigation Services
IPV	Intimate Partner Violence
M&E	Monitoring and Evaluations
MOA	Memorandum of Agreement
MSM	Men/Man Who Have Sex with Men
NAT	Nucleic Acid Test
NIC	Never in Care
NHAS	National HIV/AIDS Strategy
NHM&E	National HIV Prevention Monitoring and Evaluation
nPEP	Non-Occupational Post-Exposure Prophylaxis
OSHA	Occupational Safety and Health Administration
OOC	Out of Care
OTL	Outreach, Testing and Linkage to Care
PEP	Post-Exposure Prophylaxis
PII	Personally Identifiable Information
PLWH	Person Living With HIV

PrEP	Pre-Exposure Prophylaxis
PS	Partner Services
PWUD	Persons Who Use Drugs
QA	Quality Assurance
QC	Quality Control
RFP	Request for Proposal
RNA	Ribonucleic Acid
SNS	Social Networking Strategy
STD/STI	Sexually Transmitted Disease/ Sexually Transmitted Infection
TA	Technical Assistance
TB	Tuberculosis

Program Principles and Overview

The following are guidelines the CT DPH should see implemented in funded agencies' own Policies and Procedures pertaining to Outreach Testing and Linkage to Care (OTL) Protocols. HIV testing programs must strive to provide high-quality services to best meet the needs of their clients and achieve their program objectives. There are certain principles and standards that should be met by all HIV testing programs in order to provide high-quality services. This chapter reviews these principles and standards, and provides links for accessing more information.

Defining Nonclinical Settings

CDC supports two primary models of HIV testing: (1) routine testing in clinical settings, and (2) focused testing in nonclinical settings. Although more HIV tests are conducted in clinical settings than in nonclinical settings, persons at high risk for HIV infection may not access healthcare services, and so it is important to utilize both strategies. This manual is intended for the focused testing in nonclinical settings, but may also be useful for HIV testing providers in clinical settings.

For the purposes of this manual, nonclinical settings are sites where medical, diagnostic, and/or treatment services are not *routinely* provided, but where select diagnostic services, such as HIV testing, are offered.[1] Increasingly, agencies are beginning to offer clinical services within nonclinical settings, making this distinction a bit blurred. Still, a key feature of nonclinical settings is their location *within* the community—whether at fixed venues, outreach sites, or in a person's home, nonclinical settings are easily accessible and comfortable for populations who might not access medical services regularly. They typically provide same-day rapid HIV testing, they might offer other HIV prevention services such as structural or behavioral interventions and social services, and they conduct recruitment services to get high-risk populations in for focused HIV testing.

Examples of nonclinical settings where HIV testing may be offered include, but are not limited to; community-based organizations (CBOs), mobile testing units, churches, bathhouses, parks, shelters, syringe services programs, health-related storefronts, homes, and other social service organizations. Agencies may choose to provide HIV testing services at multiple venue types to offer a diverse range of options, to better identify high-risk clients, and to meet the needs of the populations they serve.

Some health departments might be considered nonclinical settings and offer focused HIV testing, while others offer clinical services and routine HIV testing. Furthermore, some health care organizations (HCOs) might provide a blend of routine and focused HIV testing, even though they are considered clinical settings. This demonstrates the complexity of distinguishing between clinical and nonclinical settings.

[1] ICF Macro, Inc. Planning and implementing HIV testing and linkage programs in non-clinical settings: a guide for program managers. http://effectiveinterventions.cdc.gov/docs/default-source/public-health-strategies-docs/HIVTestingImplementationGuide_Final.pdf. Published 2012. Accessed May 11, 2015.

HIV Outreach, Testing, and Linkage to Care (OTL)

HIV Outreach, Testing and Linkage to Care is a client-based HIV Prevention methodology centered on meeting the client where they are at. Several outreach approaches such as social network outreach, routine offering of HIV counseling and testing in clinical and non-clinical settings, social marketing, partner services, etc., are used to find and engage PLWHA out of care or episodically in care and connect them to care, including medical and other clinical care, support services, peer support and sexual assault and domestic violence survivor services.

Funding for HIV testing provided by DPH is reserved for individuals at high risk for HIV infection and for those who have no other resources to pay for testing. **Therefore, those requesting HIV testing through DPH contracted sites should be screened to determine that there is a sufficient risk for HIV or lack of health insurance or other means to pay for testing.** Those who are not eligible to receive testing through a DPH contracted OTL site due to low risk should be referred to another resource such as Planned Parenthood, private physician, or an over-the-counter HIV Test Collection Kit. Ultimately, no one should be turned away without exploring other testing options. Contracted programs may actually wish to purchase the Home Collection Kits for low risk individuals who request testing. HIV testing performed through a DPH contracted OTL site is based on focused behavioral risk and not on medical diagnostic criteria. Therefore, those who present with symptoms should also be referred and linked to a health care provider.

Once the testing stage has been completed, the result will determine the client's linkage to services. Clients who have a reactive preliminary HIV test (rapid test) will be required to submit a blood sample to a lab for a supplemental test for confirmation and linked to a HIV provider, should the supplemental test result be positive. Clients who receive a negative preliminary HIV test result will be evaluated for PrEP, mental health and other social services and linked to the appropriate support provider.

Comprehensive Prevention for Positives (CPP)

CPP is a set of strategies that integrates HIV prevention and the care and support of people living with HIV/AIDS (PLWHA). These strategies use health promotion and harm reduction approaches to support PLWHA and their partners in their efforts to practice risk reduction and to avoid HIV, STI, and viral hepatitis infection and/or transmission.

Through individual interventions and routine encounters with care and support service providers, PLWHA and their partners are routinely offered opportunities to assess the risks associated with personal behaviors and life circumstances. Group interventions and peer support are offered to help develop communication and other risk-reduction skills and address factors that can influence risk behaviors and overall physical and mental health. Community- level interventions that utilize print media, the Internet and other public health social marketing campaigns are used to promote the adoption of community norms that: (1) motivate individuals to learn their HIV status and access clinical care and support services; (2) support disclosure of HIV status between sex and drug-using partner; and (3) encourage individuals to take responsibility for and control of their health and the health of their partners.

Comprehensive Prevention for Positives services are a policy shift in the way services are provided to PLWHA. At times for people who are positive, prevention is not a distinct category of service but represents an integral part of their care. Simply put, prevention for HIV positive individuals complements and completes the standard of care for PLWHA.

CPP is composed of the following components:

- Finding and engaging PLWHA never or episodically in care. DPH supports activities such as Data to Care (D2C) that emphasizes engaging people who are out of care (OOC) and never in care (NIC)
- Linking PWLHA to medical and other clinical care, peer support, and support services
- Offering risk assessment and prevention counseling
- Providing partner services
- Assisting in the maintenance of care and risk reduction consistently over time.

These components connect the entire HIV/AIDS service delivery system and multiple interventions must be utilized within prevention and education, support services, and clinical care in order to implement them.

Focused Recruitment

This section provides information on focused recruitment for HIV testing and PrEP services. Focused recruitment is the process by which persons from focused populations are located, engaged, and motivated to access HIV prevention services. Regardless of whether HIV testing providers are directly involved in focused recruitment, they should be aware of how their HIV testing services are messaged in the community and how clients reach them for services.

Defining 'Focused'

The term '*Focused*', in Focused Recruitment, is the process for defining how you will direct your HIV prevention services to identify persons who are unaware of their HIV status and who are at greatest risk for HIV infection. Appropriately focusing your HIV prevention services to these highest-risk populations is necessary for maximizing resources, and for identifying undiagnosed HIV-positive persons in need of HIV medical care, treatment, and prevention services. Focusing on the populations currently impacted the most will help you identify high-risk HIV-negative persons needing important HIV prevention services, such as PrEP, non-occupational post exposure prophylaxis (nPEP), and other social and behavioral interventions.

In nonclinical settings, it is important to focus your services to identify high-risk individuals who do not access health care services or who may not otherwise have access to HIV testing in clinical settings— these are the persons who may benefit most from HIV testing services in nonclinical settings, and so these are the persons you should attempt to recruit into your program. Additionally, in defining your focus population and how to reach them, your program should consult multiple data sources, including local epidemiologic and surveillance data, recent programmatic monitoring and evaluation data, and your local district's Getting to Zero Initiative Plan https://gettingtozeroct.org/ (if located in Hartford, New Haven, Waterbury, Bridgeport, or Stamford). Members of your focus population, agency staff, and other service providers can also be important sources of information for identifying high-risk populations, where they congregate in the community, and the best ways of reaching them. Key informant interviews, which are brief interviews to obtain feedback from these groups, can be used for this purpose.

Each agency will need to define or segment their focus populations, which should include both the primary focus population and the secondary focus population (or subpopulation). In order to narrow the overall focus population to reach persons most at risk for HIV infection, agencies will need to know what high-risk behaviors and other factors are related to increased risk in the community, engaging in these behaviors or affected by these factors, and where to identify the populations. This will help agencies tailor messages and services in a way that resonate with the identified focus population and plan for how to best reach them.

To learn who the highest populations at risk for HIV infection are, please visit https://www.cdc.gov/hiv/group/index.html.

Defining Recruitment

Recruitment begins once an agency has defined the focus population and identified where and how to reach them (i.e., phone apps, social media, etc.). Community assessment or formative evaluation can provide valuable information on recruitment, given the dynamics of different communities, and the potential for certain strategies to work better than others with high-risk groups.

Your agency will need to develop a recruitment plan that outlines **when**, **where**, and **how** recruitment of the focus population will be done. The plan should include ideas about where to reach the focus population, as well as the specific recruitment strategies and messages that will be used for reaching them and engaging them in HIV testing and linkage to PrEP. Agencies might find that a particular focus population is accessible at a physical location (e.g., a particular neighborhood, bar, or weekly meeting) or in a virtual space (e.g., Internet chat group, social media).

Once your agency has defined the recruitment strategies to be used to engage the focus population and outlined these in the agency plan, agency staff should pilot these strategies and make refinements based on the results. Even after implementing recruitment strategies, agency staff should routinely monitor HIV prevention services to determine if they are meeting goals, and make adjustments to the recruitment strategies as needed. For example, if it is found over the course of 1 month that the staff have not tested anyone who is HIV-positive, the agency might need to revise the recruitment strategies to better reach persons with undiagnosed HIV infection or at high-risk for acquiring HIV infection.

Recruitment Strategies

Agencies should aim to deliver strategic, culturally competent, community-based recruitment strategies that engage the focus population and motivate them to access HIV testing services. Organizations should collaborate with other organizations that have a history of working with and recruiting the focus populations. They should seek input from community stakeholders, such as Community Advisory Boards, to select the most appropriate program promotion and recruitment strategies. Community stakeholders can also be useful for crafting recruitment messages, which may focus on increasing public awareness of the agency's services, destigmatizing HIV and HIV testing, and providing key information about HIV and HIV testing.

The 6 primary categories of recruitment strategies are the following:

1. Street-based and venue-based outreach
2. Internet outreach
3. Internal referrals
4. External referrals
5. Social networking
6. Social marketing

Street-Based and Venue-Based Outreach

Street-based and **venue-based** outreach are done by engaging the focus population in their own environment, such as a particular street, neighborhood, hot spot, or venue (e.g., a bar, hotel, or community center). Outreach workers, who may include HIV testing providers, aim to reach the focus population with key messages about HIV and HIV testing. HIV testing services may also be offered in conjunction with street- and venue-based outreach, if appropriate, and some agencies will bring a mobile testing unit, such as a van or tent, to provide HIV testing for the focus population.

Internet Outreach

Internet outreach involves reaching the focus population through online venues, such as chat rooms, social networking sites, hook-up sites, and mobile applications. Agencies can promote HIV testing services including couples or partner testing through these approaches; provide information about HIV prevention, care, and treatment; or schedule appointments for clients seeking HIV testing. Internet- based outreach may be especially useful for reaching young people and MSM who do not identify as gay or who cannot be found in traditional outreach settings.

Internal Referrals

Internal referrals means accessing the focus population through other services offered at the HIV testing agency, such as syringe services programs, substance abuse programs, mental health services, evidence-based HIV prevention interventions, sexually transmitted disease (STD) testing and treatment programs, and HIV medical care (for partners of people already in care). This approach can be successful, but persons with high-risk behaviors may not access these services independently, so additional recruitment strategies should also be used.

External Referrals

External referrals means that persons from the focus population are referred to HIV testing services by agencies outside the HIV testing program. External agencies may include syringe services programs, substance abuse programs, mental health services, evidence-based HIV prevention interventions, STD testing and treatment programs, HIV medical care, and homeless shelters. These offsite programs identify high-risk clients who are accessing their services and send them to your agency for HIV testing. Building strong partnerships with external agencies that tend to serve high-risk clients is important, as is sharing information with them about how to make appropriate referrals to your program.

Social Networking Strategy

Social Networking Strategy (SNS) is a peer-driven approach to recruitment that involves identifying HIV- positive or high-risk HIV-negative persons from the community to serve as "recruiters" for your agency. Recruiters deliver key messages and encourage HIV testing among high-risk persons in their social, sexual, or drug-using networks. They may use coupons or invitations as a way of documenting that they have delivered these messages to potential clients. The recruiters are trained or "coached" on the best approaches to reach their peers, including who should be reached through this approach and what messages can motivate their peers to be tested for HIV. Partner referral is a type of social networking that involves recruiters referring their sexual partners to an HIV testing program. Recruiters may refer their sexual partners to be tested alone, or recruiters may accompany their partners and be tested together, as outlined in Chapter 6 on Couples HIV Testing and Counseling.

Social Marketing

Social marketing is the use of media (e.g., flyers and brochures, posters, print advertisements, radio and television advertisements, or Internet advertisements) to recruit clients into HIV testing programs.

Organizations can develop their own social marketing campaigns but are encouraged to use existing resources, such as those available from Positive Prevention (www.PositivePreventionCT.org) and the CDC, and tailor them to their jurisdiction's specific requirements. Materials are available through the Community Distribution Center at https://harmreduction-ct.org/ccdcp.html . CDC's Act Against AIDS campaign materials can be accessed at http://www.cdc.gov/actagainstaids/. Additional materials are available at http://effectiveinterventions.cdc.gov/.

Implementing Recruitment

In order to achieve the best results, agencies should employ multiple recruitment strategies to reach the focus populations. Agencies may even choose to use all 6 recruitment strategies because they each have their own benefits and potential for reaching different subgroups of the focus population. When selecting recruitment strategies your agency should consider staff safety, agency capacity, and availability of resources.

Recruitment of the focus population is essential to the success of a high-impact HIV testing program. In order to have an effective and innovative program, resources should be dedicated to carrying out the recruitment plan. Your program may have the most success if you:

- Hire and train specific recruitment staff who are separate from HIV testing staff
- Build partnerships in the community to ensure multidirectional referrals and expand your reach
- Use innovative approaches for reaching the focus population through Internet and social media

- Offer incentives to reach previously unreached focus populations, generate interest in new services, or obtain buy-in for testing at, or around, high-risk venues (e.g., bars, clubs) where clients might need extra motivation to access HIV testing.

Incentives

Incentives should not be utilized as a means of recruiting participants to be tested for HIV. Any agency wishing to use incentives for other means besides HIV testing must develop an incentive policy for DPH review that aligns with the DPH Incentive Policy. (https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/dph/aids_and_chronic/prevention/pdf/IncentivePolicypdf.pdf?la=en).

Agencies using SNS approaches may deliver incentives to recruiters when the clients they recruit show up for HIV testing. Recruiters should be encouraged to refer clients from the focus population and may wish to specifically focus on referring first-time testers, couples or partners, and high-risk persons in the social networks of HIV-positive clients.

Challenges to using incentives include the potential to attract repeat testers who are more interested in the incentive than the HIV test, interagency competition, and sustainability. In developing an incentive plan, agencies should identify an appropriate incentive rate for reaching the focus population. It may be useful to consult with community advisory boards or clients to elicit feedback on appropriate incentives for HIV testing.

Agencies should regularly revisit and refine their recruitment strategies. If, through monitoring and evaluation (M&E), you discover that your testing program is not reaching the focus population or you are not on track to meet your goals, you will need to try different recruitment strategies.

Boundaries

Maintaining professional boundaries is a basic necessity pertaining to HIV prevention services, especially recruitment. Please refer to your agency's policy and procedure protocol. **The act of promising or enticing potential clients with sexual or monetary incentives in return for getting a HIV test or PrEP referral are not allowed by agencies funded by CT DPH.** Understanding the difference between client and friend relationships is crucial for establishing a smooth-flowing program. When friends are recruited to participate in your agency's services, it is strongly recommended that a coworker or colleague work with that participant, if available. Friends and family members may obstruct the truth when asked about high-risk activities (e.g., sexual health intake, drug use, etc.) in an effort to maintain the reputation or image they want you to have of them, rather than confidentially disclosing the truth to someone they do not know.

Peer workers who utilize MSM geo-location social applications on their own time for recreational purposes must establish professional boundaries while utilizing the same applications for work purposes. Using an account created by the funded agency is an example of keeping personal and

professional boundaries in place. While on the agency's account, anyone who is being engaged for HIV Prevention services is off limits for recreational/non-professional relations. Please speak with your supervisor if clarification is needed on this topic.

Documentation

Documentation of Focused Recruitment efforts is necessary for an effective program as it serves two primary functions. Agencies are encouraged to create their own tracking forms to document their efforts.

1. **Track Efforts:** Keeping track of the number of individuals having been reached is required by the CT DPH for every Tri-Annual report.

2. **Review Efforts:** Referring to previous efforts can provide a clear picture on what is working and not working when evaluating goal achievement and if any changes need to be made. If there is a location, time of year, event, or other variable that helps or inhibits your agency completing goals, this information is very valuable.

HIV Testing Policies

Guiding Principles

Staff conducting HIV testing should be trained in accordance with state and local requirements before providing services to clients.
The following principles guide the provision of HIV testing in nonclinical settings, and HIV testing providers should ensure that these are met:

1. HIV testing is **voluntary**; clients have elected to be tested of their own accord, and they are not coerced or forced to be tested. Clients have the right to decline services.
2. Clients give their expressed written **informed consent** to be tested; they clearly understand basic information about HIV and HIV testing, and they provide written agreement to be tested for HIV.
3. HIV testing can be either **confidential** (name is given) or **anonymous** (name is not given); although confidential testing is preferred for facilitating linkage to care for newly diagnosed HIV-positive clients, some clients may only test if they can do so anonymously. Clients should understand the benefits of confidential testing compared to anonymous testing, including what measures are in place to protect their confidentiality, how their personally identifiable information will be protected, and who will know their test results(e.g., the local health department if the results are HIV-positive). For more information or to determine if anonymous testing is an option for your clients, consult with your supervisor and/or DPH Contract Manager.
4. HIV testing services should be **client-centered**; that is, services should be focused on the client's concerns and circumstances. Services should also be **culturally competent** with respect to race, ethnicity, gender, sexual orientation, age, language, literacy, relationship status, and other relevant factors.
5. All clients testing HIV-positive should be referred and **linked to Partner Services and HIV Medical Care**, and these linkages should be tracked to ensure timely linkage and successful enrollment in care.

Special Circumstances for Consent

Agencies should establish policies about testing people who are under the influence of alcohol and or drugs. Policies should include information to help counselors understand what to do if clients are under the influence and whether or not to test. In order to get an HIV test CDC requires that people being tested are able to give consent. If testing staff have reason to believe that a client is intoxicated or not of sound mind to give consent, staff should ask a supervisor or other colleague for assistance.

Persons who have a mental health disorders may not be able to give their own consent for HIV testing. Agencies will need to evaluate who to test based on their policies on a need to need basis.

Ethical Standards

Agencies should establish an ethical code of conduct for their HIV testing services, which should be read and understood by all testing providers. This code of conduct should clarify that HIV testing providers must protect client confidentiality, should not use or be under the influence of alcohol or drugs while on duty; should not have sex with clients; should not exchange money with clients; or engage in other inappropriate behavior with clients. Agencies should establish and enforce these boundaries to protect their staff and their clients, and to ensure clients receive high-quality HIV testing services.

Policies and Legal Considerations

HIV testing providers should understand and provide services in accordance with their agency policies and state and local policies and laws. The policies and laws providers should be familiar with include, but are not limited to:

- Authorization for agencies to provide HIV testing
- Provider training and certification to perform HIV testing
- Who can consent to and receive HIV testing (e.g., teenagers or intoxicated persons)
- Provision of confidential vs. anonymous testing
- Record keeping and ensuring confidentiality
- Reporting HIV testing results
- Provision of partner services (elicitation, notification services, etc.)
- Laboratory certifications or licensure
- Quality assurance procedures for HIV testing

Laboratory Certificate Requirements

Nonclinical HIV testing sites using waived rapid HIV tests must either obtain their own certificate of waiver under CLIA (the Clinical Laboratory Improvement Amendments of 1988), or establish an agreement to work under the CLIA certificate of an existing laboratory. CLIA outlines quality standards for laboratory testing—including rapid HIV testing—to ensure the accuracy, reliability, and timeliness of patient test results. More information about CLIA certification and CLIA-waived tests can be found on CDC's HIV/AIDS website (https://www.cdc.gov/clia/index.html).

All sites planning to offer waived rapid HIV testing not already CLIA-certified, must obtain a Certificate of Waiver or be included under a multiple site exception, such as limited public health testing or mobile testing. The CLIA form must be completed by completing information on the facility type (select from a list), hours of operation, estimated annual number of waived tests to be performed, the type of control (nonprofit, for profit or government control) and the total number of individuals involved in performing testing (*See Appendixes*).

The facility owner or laboratory director must sign the form. CLIA waiver applications can be obtained by contacting Kim Hriceniak, RN, C, BSN, at the State Department of Public Health. Mail the completed form to Kim Hriceniak at the State Department of Public Health, Facility Licensing and Investigation Section, 410 Capitol Avenue, MS# 12FLIS, P.O. Box 340308, Hartford, CT 06134. For more information on obtaining a CLIA certificate, click on the website at http://www.cms.hhs.gov/CLIA. After the completed form is processed by the State agency, a fee of $150 will be assessed for a Certificate of Waiver. The certificate is valid for two years.

Health Information Compliance

All health care providers—including HIV testing providers—must comply with federal and state laws that protect patients' health information, such as those set out in the Health Information Portability and Accountability Act of 1996 (HIPAA). HIPAA provides clients and patients access to their medical records and gives them control over how their health information is used and disclosed. Clients and patients can give permission to share their health information with anyone, including friends, family members, and organizations that provide referral services. This means that couples who wish to be tested and receive their results together may do so under HIPAA if both partners are in agreement.

Data Security and Confidentiality

All data collected by nonclinical HIV testing sites should adhere to the standards outlined in Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs. These guidelines provide recommendations related to record keeping, data collection, data management, and data security.

Universal Precautions for Employee and Consumer Safety

The Occupational Safety and Health Administration (OSHA) has established basic precautions designed to keep employees and consumers safe when they might come into contact with blood or other body fluids (e.g., saliva, urine). These precautions are known as "universal precautions" and should be observed by all HIV testing providers. They include the following:

- Wash hands or other skin surfaces immediately before and after handling blood or other body fluids. If soap and water is not available, alcohol-based hand sanitizer may be used.
- Use disposable gloves (preferably nitrile); change gloves between clients.
- Do not eat, drink, apply makeup, or handle contact lenses in the testing area.
- Do not keep food or drink in refrigerators, containers, shelves, cabinets, or countertops where potentially infectious materials are present.
- Dispose of lancets, needles, or other fluid-touched items (e.g., gauze) in proper biohazard containers.
- Disinfect all work surfaces and items before and after testing with 10% bleach solution or Environmental Protection Agency-approved disinfectant.

In the context of HIV testing, the most likely occupational exposure will be through blood collected via fingerstick or blood draw, needlestick injuries while collecting specimens, or through sharp injuries.
Other staff, such as janitorial staff who clean up the areas where testing is conducted, may also be occupationally exposed. Agencies must protect workers who may come into contact with blood or other body fluids, and make arrangements for safe and proper disposal of all HIV testing waste.

If you come into contact with body fluids, report this exposure to your supervisor immediately and seek medical guidance to initiate post exposure prophylaxis (PEP).

Provider safety

Agencies should establish policies and procedures to keep staff and volunteers safe in HIV testing settings. These policies may include language about the number of staff required to be onsite; service provision hours; emergency preparedness; and staff conduct in outreach sites, mobile testing units, and HIV testing events.

Quality Assurance

Establishing and implementing Quality Assurance (QA) activities can help ensure that agencies are delivering accurate test results, meeting program objectives, and delivering services according to established procedures. Each agency should develop a QA plan outlining their agency's QA activities, which might include:

- Running test kit controls according to the manufacturer's protocols
- Keeping both room and refrigerator temperature logs
- Conducting HIV testing data reviews, including medical charts and client data forms
- Conducting role plays with peers, or between supervisors and peers
- Holding team meetings to review activities, discuss problems and concerns, and identify solutions
- Case conferencing to discuss challenging client cases and identify solutions
- Eliciting client feedback through surveys or interviews
- Conducting refresher trainings
- Performing direct observation of HIV testing sessions (with client permission)
- Receiving implementation support from CBA partners
- Reviewing client informational materials to ensure cultural appropriateness and accuracy
- Reviewing community referral and linkage resources, and establishing partnerships

QA activities are most effective when conducted on a regular basis, and when a combination of approaches is used. QA will be coordinated with state health department staff.

To ensure the accuracy of HIV test results, it is important that tests be performed correctly and consistently in accordance with written procedures and the manufacturer's protocols. Agencies should have HIV testing procedures that describe the following:

- Safety precautions to protect clients and testing personnel.
- Quality control (QC) procedures, including frequency of running external quality controls, documentation of QC results, and protocols for follow-up testing for clients with initial HIV-positive results.
- Materials and equipment required to support specimen collection, test performance, and documentation of test results.
- Specific steps required to perform the test correctly, as outlined in the product insert. There can be no deviations from what is in the product insert, or results may be invalid.
- Issues that may affect the accuracy of test results. These are listed in the product insert.
- Plans for addressing QC results that are not within acceptable limits. If there are issues that cannot be addressed, call the manufacturer's customer service line.

Monitoring and Evaluation

Monitoring and Evaluation (M&E) activities assess the resources that go into a program (e.g., staff, funding), the services provided (e.g., tests provided, referrals provided), and the results of the program (e.g., new HIV diagnoses, successful linkage to care) to determine whether the program is meeting its objectives. Every HIV testing program should conduct M&E activities to assess and track program performance, to identify areas in need of improvement, and to ensure accountability to stakeholders. HIV testing providers play a critical role in M&E activities because they are responsible for the accuracy of client-level data and reporting.

M&E begins with establishing HIV testing program targets based on formative work, your agency's capacity for client flow, and requirements established by your funders. Agencies should establish goals for the total number of clients tested per month, the proportion of testing clients who represent focus populations, the proportion of clients who are tested as couples, and/or the total number of new HIV diagnoses per month. Much of this work will be established in advance by your agency's program manager.

Once your agency has established program goals agencies will need to collect data on each client in order to assess whether goals are being met. This might include demographics, HIV risk behavior, HIV test results, and linkage to HIV medical care. Again, the type of data agencies are required to collect will be established in advance by your testing agency, health department, CDC, or other funding agencies. Standard data collection tools (e.g., forms, logbooks) should be used.

Once client-level data are collected, they should be reviewed for completeness and accuracy, and stored in a secure location. These data should be compiled on a regular basis (e.g., monthly), and trends should be tracked over time. Reports should be produced and shared with stakeholders, including HIV testing program staff, board of directors, health department, CDC, and other funding agencies. Personally identifiable information (PII) such as client names and locating information should not be disclosed in these aggregate reports.

HIV testing programs should establish a process for reviewing these data on a regular basis to determine whether the agency is meeting established goals and objectives and make adjustments to program strategies accordingly. For example, if your agency's monthly report illustrates that only 40% of HIV testing clients are from the focus population, your staff may wish to implement new recruitment approaches the following month to increase that number to 60%. Including all stakeholders in the process of data sharing and review ensures that everyone has the same understandingof program targets and achievements and gets everyone involved in identifying solutions for program improvement. Some agencies may wish to appoint a data monitor to be in charge of data quality and reporting, but all staff have a role in ensuring successful M&E.

State of Connecticut Testing Laws

Testing of Minors

In 1996, Section 19a-952 of the AIDS Confidentiality Law was amended to include the testing and treatment of minors for HIV or AIDS. The section is summarized as follows:

Counseling, testing and treatment of a minor for HIV requires the consent of a parent or guardian, except:

a) If notification would result in denial of treatment

b) If fear of the result of notification would lead the minor not to seek or continue treatment

To treat the minor without notification, the minor must make such a request, and the counselor must fully document his/her reasons for the request. The minor must sign the documentation and it must be included in the client record.

Once confidential treatment is promised:

a) No relevant information can be divulged unless the minor consents

b) Bills should not be sent to the parents' or guardian residence unless the minor agrees in advance

c) The minor is responsible for all costs and expenses

All HIV prevention funds for publicly funded counseling and testing sites should be focused to the voluntary HIV testing of adults and adolescents whose personal behavior puts them at risk for HIV or AIDS. Especially for those who are uninsured, under-insured and low-income individuals who cannot pay for HIV testing.

Under no circumstances should HIV testing be provided to individuals under the age of 13 years. Youth 12 years and under should be referred to their pediatrician or comprehensive health care facility.

Deaf and Hard of Hearing

As part of a culturally competent risk assessment, counselors should evaluate the appropriate interpretation needs of the deaf or hearing-impaired such as American Sign Language (ASL) or TTY equipment. Currently TTY equipment is located in the following health departments: Hartford, Bridgeport, New Britain, and New Haven. Appropriate arrangements should be made by the agency to accommodate the needs of deaf and hearing-impaired clients.

Sexual Assault Survivors

HIV is a concern for rape and sexual assault survivors. This violence needs to be considered a risk factor for contracting HIV/AIDS. Although the risk for one-time sexual assault is considered to be low, the benefit of effective HIV Prevention Counseling and Testing can greatly help sexual assault victims in the long run. The State of Connecticut collaborates with CT Alliance to End Sexual Violence http://endsexualviolencect.org/ to ensure that support and services for sexual assault victims is readily accessible and culturally appropriate. Legislation allows for HIV testing of the alleged perpetrator upon request of the victim of sexual assault.

The following information will provide counselors and program supervisors with the current state statute and policy on disclosing offender HIV test results to the victim.

More information on this can be found at https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/dph/aids_and_chronic/prevention/pdf/SABrochurepdf.pdf?la=en

Disclosures

Individuals that come for testing may or may not disclose a history of sexual abuse even if they have been sexually assaulted and referred to a testing site by a sexual assault counselor/advocate.

In certain cases, sexual assault survivors may seek the services of the HIV counseling/testing site to have the testing results of the person charged with assaulting them disclosed. (Please see special consideration).

If in the course of testing, someone does disclose that they were raped or assaulted, the HIV testers supportive and non-judgmental response can have a positive impact in the healing of the client and empowers clients' to understand that information and support are available to them if needed.

OTL must not attempt to counsel on sexual assault but should aid victims and make referrals to a trained Sexual Assault Crisis Counselor, as appropriate. In addition, counselors are encouraged to build connections with the local SACS programs in order to provide these services more effectively. SACS programs provide the following free and confidential services:

- 24-hour hotline (English and Spanish) with immediate access to certified counselor/advocates
- Individual Counseling
- Accompaniment and advocacy throughout the medical and police system
- Preparation, accompaniment, and advocacy throughout the court system
- Information and referral for other needs
- Support groups
- SACC do not release names or information about a client without the expressed consent of the individual. *

Overview of State Ordered Testing

The CT AIDS Confidentiality Law Section 19a-582e8 was amended to allow for the HIV testing of individuals' accused of a Sexual Assault. A summary of the law is as follows:

A defendant accused of a sexual assault may be tested for HIV without consent if a:

1. Sexual assault victim requests that the Connecticut criminal court or juvenile court order such tests or;
2. Judge orders such testing at his/her discretion before final sentencing.

The results will be disclosed to the victim (by the court or their designee) if the test was at the victim's request and only after the offender has received the result. All other aspects of the AIDS confidentiality Law must be followed. The testing of victims of sexual assault should be done as a standard of practice.

Offender Testing

When an offender is accused of a violation of section 53a-70 (Sexual Assault, 1st degree), the rape victim may request that the offender test for HIV. The victim will then complete the Request by Victim of Sexual Act to Test Defendant for AIDS/HIV Form, JD-CR-105. Offenders will be tested and the results will be disseminated at a location selected by the victim.

Gives Information to Victims

When a court orders an HIV test at the request of a person charged with a sexual assault crime, the court shall provide the victim with the Notice to and Information for Victim Re: Court ordered HIV /AIDS Test of Defendant Form, JD-CR-139 which includes the following:

1. Educational materials about human immunodeficiency virus and acquired immune deficiency syndrome developed by the Department of Public Health.
2. Information about and referral to HIV testing and counseling for victims of sexual assault.
3. Referrals and information regarding SACS programs.

Victim Retrieval of Court Ordered HIV Test Results

A victim of sexual assault has two options to retrieve court ordered HIV Test Results. The victim may designate a health care provider chosen by the victim or an HIV testing and counseling site funded by the DPH to receive the results of such test on behalf of the victim. At that the time, the victim will complete the Victim's Designation of Receiver for Defendant's HIV/AIDS Test Results Form, JD-CR 140.

1. Health Care Provider- If the victim has designated a Health Care Provider not currently funded by the State of CT Department of Public Health, the designated health care provider shall disclose the test results to the victim.
2. DPH funded HIV Counseling and Testing Provider Discloses Test Results- If the victim has designated a DPH funded HIV Counseling and Testing Provider for the retrieval of their court ordered HIV test results, they must complete Notice to Victim's Designee to Receive Defendant's HIV/AIDS Test Results Form, JD-CR-141. The court will send a copy of the offender result to the funded DPH Counseling and Testing Provider. The victim will then be instructed to by the court to contact the site for the retrieval of their results and will make arrangements with the site for an appointment.

At that time, a professionally trained counselor will provide counseling about HIV and acquired immune deficiency syndrome, risk reduction counseling, and offer referrals if appropriate.

Protocol for Court Ordered HIV Testing:

The DPH in cooperation with the Judicial Department will test individuals sent with a court order for HIV testing under this law. The policy for HIV testing individuals accused of sexual assault are as follows:

If the offender has been charged with a sexual assault crime, the sexual assault victim can ask the court to order the offender be tested for HIV. Forms for making the request are available through the court clerk's office. As of October 1, 2004, the law allows the sexual assault victim to choose a health care provider or DPH funded HIV testing site to receive the offender's test results and disclose them to the sexual victim.

1. **Ask the client for the court order:** If a client comes to your site and states that they have been sent by the court, by their attorney, by a judge or other legal entity **DO NOT TEST WITHOUT THE PAPER WORK**.
2. **Court orders should site the Connecticut general statutes for sexual assault HIV Testing**: See attached Law. Courts may use a generic court order, or one specifically developed for HIV Testing of defendants' accused of sexual assault.
3. **Court orders must be signed by a judge:** The request may have been initiated by someone other than the judge, e.g. an attorney, probation officer, victim advocate, etc. However, a judge must sign it.
4. **Fill out the required DPH Data forms:** Provide Pre-Test Counseling and HIV Testing just as you would for any other client.
5. **Schedule client for posttest counseling:** Client will return to you for their post test result and follow-up.
6. **Send court order in a sealed envelope with blood specimen to the lab:** Write "Court Order" on the envelope. Do not keep a copy of the court order. You have DPH assessment information about the client**.**
7. **It is the court's responsibility to notify the victim or others regarding the result:** The Counseling & Testing site responsibility is as usual to the client being tested.
8. **The lab will send the HIV result and the court order back to the judge:** The site has no responsibility to the court. The laboratory is responsible to get the result back to the judge and keep a copy for their files.
9. **If STD screening is also ordered, the STD clinic needs the original:** Make a copy and forward to the lab as mentioned above. Write on the envelope where you sent client for STD Testing (i.e., Hill Health Center).
10. **Make it easy for the client:** All Planned Parenthood sites can do both HIV Testing and STD court ordered cultures for screening. (STD Clinics in the Health Departments do not do cultures). Other federally funded HIV programs that can do both HIV testing and STD screening are the local hospitals and community health centers (see attached lists).
11. Counselors should consider sending the client to one of these locations if both tests are ordered.

Resource Information:

Connecticut Alliance to End Sexual Violence
http://endsexualviolencect.org/
96 Pitkin Street
East Hartford, CT 06108 860.282.9881
Toll Free Hotline: 1.888.999.5545 English 1.888.568.8332 Spanish

Domestic Violence and Intimate Partner Violence (IPV)

Domestic/intimate partner violence can happen to anyone. Tragically, one in four women will be abused during her lifetime. While most domestic violence involves men assaulting women, it can also involve men assaulting their male partners, or women assaulting their male or female partners.
Domestic violence is more common in the lesbian community than formerly believed (Trisdale, 2005). What constitutes domestic/intimate partner violence?

Violence perpetrated by an intimate partner is widespread globally. It includes:

- Physical violence (e.g. slaps, punches, kicks, assaults with a weapon, homicide);
- Sexual violence (e.g. rape, coercion and abuse include use of physical force, verbal threats, and harassment to have sex, unwanted touching or physical advances, forced participation in pornography or other degrading acts that often persist over time and are accompanied by threats on part of the perpetrator);
- Psychological violence (e.g. belittling the woman, preventing her from seeing family and friends, intimidation, withholding resources, preventing her from working or confiscating her earnings).

Screening for Domestic/Intimate Partner Violence

If a person is a victim of abuse, he or she may be reluctant to share that information therefore screening must take place during the initial risk assessment. The core of the domestic violence screening is a simple straightforward question: "What response would you anticipate from your partner if he or she were notified of possible exposure to HIV?" If the patient identifies concerns about the partner's reaction, a series of follow-up questions should be asked, such as:

Have you ever felt afraid of your partner? Has your partner ever pushed, grabbed, slapped, choked or kicked you?

Based on what you have told me, do you think that notification of a positive HIV result to this partner will have a severe negative effect on your physical health and safety or that of your children or someone close to you?

Communication is necessary to ensure that the client's safety continues to be the priority in decisions about proceeding with HIV testing and partner notification. If there is a risk of any form of domestic violence, the counselor should refer the client for domestic violence services and partner notification should be deferred.

HIV Incidence Surveillance Program

Newly diagnosed cases of HIV infection are required to be reported to the Department of Public Health, HIV/AIDS Surveillance Program. HIV cases are reported using the *Instructions for HIV Counselors and the Adult HIV Confidential Case report Form (CRF) (See Appendixes)* – designed specifically for use by HIV Testers. HIV/AIDS Surveillance Program staff will mail a CRF to the counselor based on results received by the DPH laboratory but you can report a case at any time. Instructions on how to complete the form can be found at the following: https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/dph/aids_and_chronic/prevention/pdf/OTLCRFinstructionspdf.pdf?la=en

Important! **The HIV Testing History (Section 10 of the CRF) needs to be completed for all clients who test positive for HIV.** For more information, please call the Department of Public Health, HIV/AIDS Surveillance Program at 860-509-7900

HIV Testing Practices

Use Best Possible Technologies and Approaches

Because one of the goals of HIV testing programs is to identify HIV infection as early as possible after exposure, programs should use testing technologies and specimens that allow for early detection. If possible, persons at highest risk should be tested for acute infection. In general, the tests used for this will be antigen/antibody combination tests used with blood specimens collected from the vein. However, it is not always feasible to have someone trained in collecting blood from a vein at nonclinical HIV testing sites, and so blood collected from a fingerstick is often used. Blood (whole blood, serum, or plasma) is the preferred specimen for HIV testing because tests conducted with blood are more sensitive for early infection than tests conducted with oral fluid. If an organization must use oral fluid for testing, it is important that clients and HIV testing providers understand the limitations.

Testing Basics

Your agency should have already selected the types of test kits that you will use to perform HIV testing, and if you will be performing HIV testing, you should receive training on how to conduct these tests. This chapter includes important information you should know about the different types of HIV test kits that are available, so that you are able to answer questions that your clients might have.

Agencies are encouraged to use the best possible testing technologies and specimens that allow them to detect HIV infection as early as possible after exposure. Immediately after infection, during what is referred to as the *eclipse* period, **no HIV test** can detect infection. Following this period is the *acute infection* period, the interval between when HIV ribonucleic acid (RNA) can first be detected using a nucleic acid test and when antibodies can first be detected. Most antibody tests cannot detect acute HIV infection, and persons with acute HIV infection can be highly infectious.

Every test has a *window period* during which the test cannot detect HIV infection. That period depends on the type of test being used, as well as the individual being tested. The window period includes the eclipse period (when no test can detect infection) up through the time when the particular test becomes reactive.

There are 3 types of HIV diagnostic tests: nucleic acid tests (NATs), antigen/antibody tests, and antibody tests. NATs detect HIV RNA directly and have the shortest window period, followed by antigen/antibody tests, and then antibody tests.

Nucleic Acid Tests

Before antibody tests are able to detect the body's response to HIV infection, NATs can detect the presence of the virus in blood. NATs can detect very early infection, as early as 10 days after infection. NATs are used for HIV testing in many laboratory settings. Additional information is available at CDC's website for U.S. HIV tests (http://www.cdc.gov/hiv/testing/).

Combination Antigen/Antibody Tests

Combination antigen/antibody tests detect both the antibody to HIV and the antigen "p24"—a protein that is part of the virus itself. Because the p24 antigen can be detected before antibodies appear, combination tests can identify very early infections. These tests—used with blood specimens collected from the vein—are recommended by CDC as the first test in the laboratory testing algorithm. Combination antigen/antibody *rapid* tests can be used for point-of-care testing but detect infection several days later than the laboratory-based combination tests. The evidence is inconclusive about the ability of combination antigen/antibody rapid tests to accurately detect the p24 antigen on whole blood specimens, and CDC has not provided recommendations about the use of these tests.

Antibody Tests

HIV antibody tests detect the presence of antibodies against HIV, which typically develop within 2 to 8 weeks after exposure to the virus. An antibody test can be conducted on a sample of blood or oral fluid. Many antibody tests are rapid tests, which means results can be returned on the same day, or within the same hour, or even within minutes. Rapid HIV antibody tests can be attractive for use in outreach settings because these settings may not be equipped to conduct venipuncture, and clients can get the results from their screening test quickly. Oral fluid antibody tests have been shown to detect infection a month or more later than blood-based tests because there is a lower concentration of HIV antibodies in oral fluid than in blood. Oral fluid is not ideal for identifying early HIV infection but may also be appealing in outreach settings because collecting oral fluid does not involve a fingerstick or venipuncture to perform the test. No antigen/antibody or nucleic acid tests are available for use with oral fluid. Blood-based rapid HIV antibody tests are widely available in most nonclinical HIV testing sites, and blood (whole blood, serum, or plasma) is the preferred specimen for HIV testing because tests conducted with blood are more likely to detect early infection than those conducted with oral fluid. If your organization must use oral fluid for testing, then you should inform HIV testing clients and patients of the limitations of this type of specimen for testing.

Preparing the HIV Testing Environment

HIV testing should be conducted in a private location where client confidentiality can be ensured and where a specimen can be collected safely and without risk of contamination. Some recommendations for establishing an ideal HIV testing environment include:

1. Room/testing space: Providers should ensure that the testing space has enough room and seating for all clients to feel comfortable and confident in their HIV testing experience.
2. Lighting: There should be enough light to allow providers to perform the test and read results accurately.

3. Temperature: Rapid HIV tests should be stored, transported, and conducted within specific temperature ranges specified by the manufacturer. HIV testing providers should check the package inserts to ensure they are adhering to these temperature specifications.

4. Surface area: Rapid HIV tests must be performed on a clean and level surface. HIV testing supplies and controls should be well organized, and no food or drink should be consumed near the testing area.

5. Storage and disposal: Most rapid HIV tests can be stored at room temperature below30°C/86°F. However, most controls used for quality assurance and quality control procedures must be stored in a refrigerator with temperature controls. HIV testing providers should maintain an inventory of testing supplies, including lot numbers, date of receipt, storage temperatures, expiration dates, and dates of use. Discard opened reagents after the manufacturer's expiration date, and do not use reagents from kits with different lot numbers interchangeably.

6. Equipment: Laboratory-based tests may require refrigeration of specimens. Refrigerators should have temperature controls, should only be used for the storage of samples and/or testing supplies, and should be labeled as such. A centrifuge will also be needed to prepare laboratory samples for testing.

7. Prevention Materials: Condoms, lubricants, and educational materials should be made available to clients in the HIV testing room as well as in the waiting area (or on display if at an outreach or community venue).

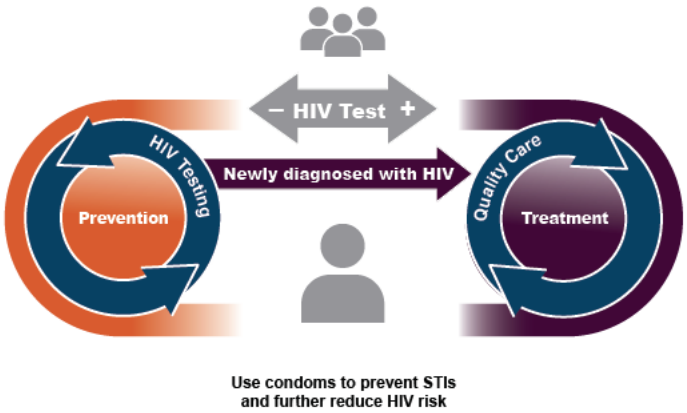
8. Supplies: Staff should have all the supplies, materials, and reference information necessary to provide HIV testing and linkage to care services, including data forms and testing logs; testing supplies and equipment; prevention and educational materials; referral and resource information; and client satisfaction or feedback questionnaires.

Testing Approaches

Status-Neutral Model

The Status-Neutral Model began in New York City in 2016, examining the ideation of a treatment model proposing the same approach to engagement in care, regardless of HIV status. The goals of this model are:

- To remove the clinical and social HIV divide between PrEP and ART
- Normalize HIV prevention and treatment
- Maintain ongoing engagement in care between patients and providers.



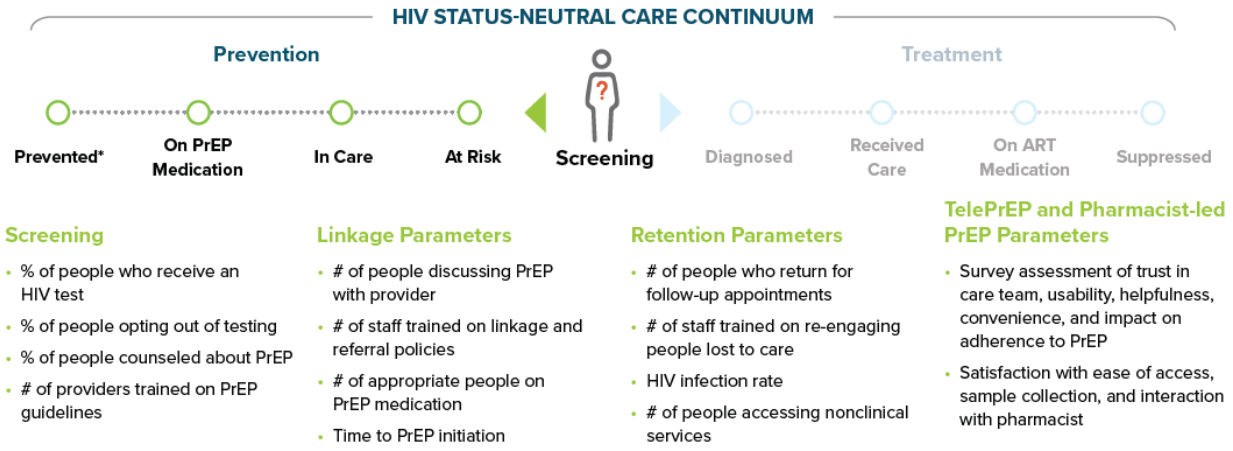
The execution of this model begins with HIV testing and offers two paths, depending on the outcome of the test. Depending on if the rapid test was reactive or non-reactive, the client would either be engaged for ART for people living with HIV or preventative strategies for people at risk for HIV, such as PrEP. After the initial engagement with the HIV Prevention Specialist, the paths become dynamic. Though efforts for preventative and quality-care services is ongoing, the end point is not a final state but a dynamic one requiring attention from both healthcare providers and patients/clients. Those without HIV consistently return for HIV testing, while those with HIV consistently return for treatment.

The CT DPH HIV Prevention Program expects funded HIV Prevention sites adopt this model into their practices.

As long as the client self-identifies as being a candidate for PrEP, regardless of their test result, they will be encouraged to get into treatment, whether it is PrEP if they are non-reactive, or ART if they are reactive.

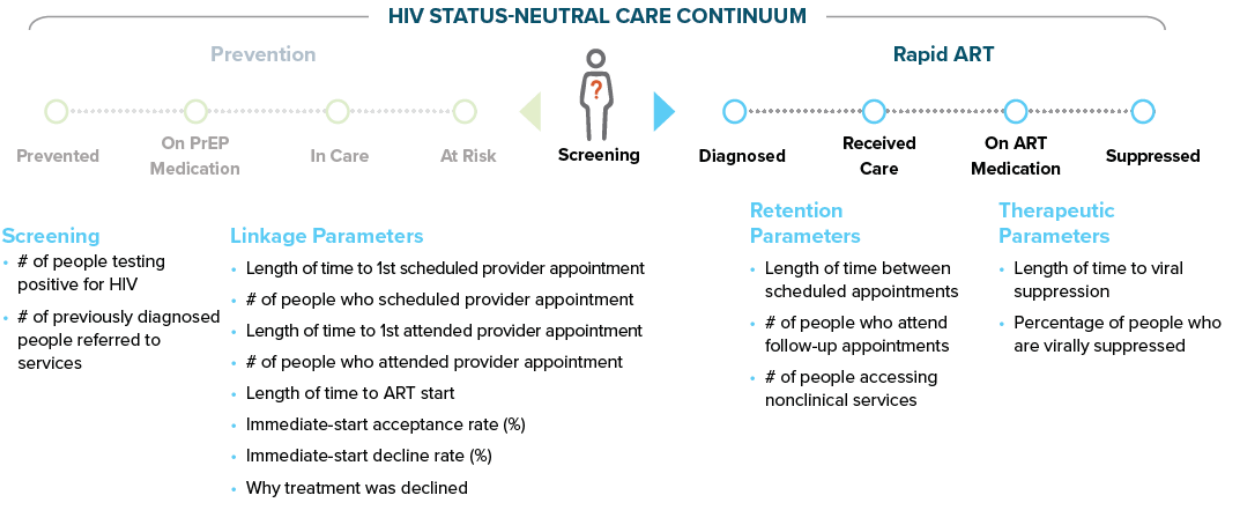
The following diagrams demonstrate the execution of the Status-Neutral Care Continuum based on the result of the HIV rapid test. Below each diagram are objectives to remain mindful of as you provide services to your clients.

NON-REACTIVE HIV TEST

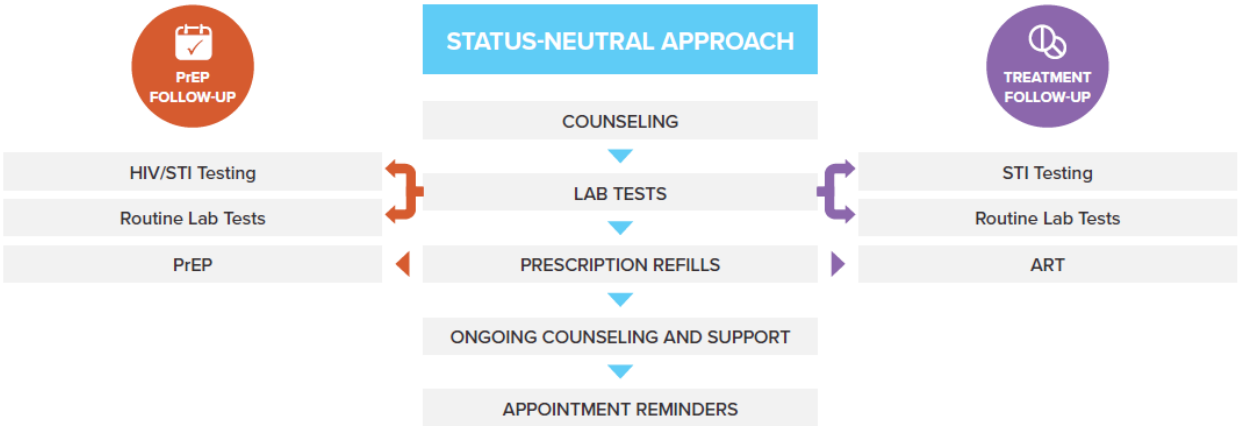


As you can see, once the client was determined non-reactive, they were determined to be a candidate for PrEP, linked into care, retained their treatment regiment, and became fully protected from infection of the HIV virus.

REACTIVE HIV TEST



Once the client is engaged into care, the same Status-Neutral approach is able to be continued. The below provides a model explaining the on-going, follow-up treatment the client should receive.



Point-of-Care Testing

Most rapid HIV testing performed in nonclinical settings is considered "point-of-care" or "point-of-contact" because the test is processed onsite where the client is receiving services. Results of rapid tests are often provided in less than 1 hour or even within minutes. The testing may be called "rapid HIV testing" or "CLIA-waived rapid HIV testing."

CLIA establishes criteria for rapid HIV tests based on 3 different levels of complexity: **waived**, **moderate complexity**, and **high complexity**. CLIA-waived rapid HIV antibody tests are the most common type of tests used in nonclinical HIV testing settings, although some nonclinical settings are also starting to incorporate CLIA-waived combination antigen/antibody rapid tests. CLIA-waived rapid HIV tests can be used in many different settings and are typically used in nonclinical settings because of their ease of use and fast test results. A list of CLIA-waived rapid HIV tests is available at http://www.cdc.gov/hiv/testing/nonclinical/.

Instructions for specimen collection, preparation, and performance of rapid HIV tests are provided by the manufacturer in the test kits. Additionally, many public health laboratories have job aids that can be adapted and used by HIV testing providers. You should always follow the manufacturer's instructions and have them available in the testing area for easy reference. If there are any questions about the test kits or how to perform the test, you should call the manufacturer's customer service number, which is provided on the product insert.

http://effectiveinterventions.cdc.gov/en/HighImpactPrevention/PublicHealthStrategies/CTR.aspx.

Self-Tests

Self-testing is an emerging area of interest among consumers and HIV-testing providers because it can be an effective method for reaching people who are not otherwise getting tested as well continuing to test clients post-COVID-19. This approach may also be helpful in reaching couples and persons in sexual relationships. Some nonclinical HIV testing sites are finding opportunities to engage with self-testing clients by being available for follow-up counseling or by actually distributing the tests and serving as a resource for clients who have completed testing and interpreted their results. Strategies for engaging persons who test positive with a self-test should be explored so they can be linked to medical care quickly.

As of November 2021, there are two HIV self-tests available on the market: the Home Access HIV-1 Test System (where a self-collected sample is mailed to a lab for testing) and the OraQuick In-home HIV test. These tests can be found for purchase online and in stores. Consumers should ensure that any HIV test advertised for home use is FDA approved before purchasing.

In-Home Testing Initiative

In March 2020, CT DPH launched the In-Home HIV Test initiative, #RequestFreeHIVTestCT, as a pilot to enhance access to free HIV self-testing for hard to reach populations, such as LGBTQ+, and people of color. The In-Home HIV Test Kit is an oral-swab rapid HIV test, that is self-administered in the privacy of one's home. In the spirit of true harm reduction philosophy, the initiative aims to meet people where they are. CT DPH HIV Prevention Program is committed to working with our community providers to continue to provide access to the prevention services during challenging times.

CT DPH developed a policy is to assist participating organizations/agencies in developing their own In-Home HIV Self-Test program. This policy provides information on how to request the In-Home HIV Self-Test Kits, how to market the program using the CT DPH social media/marketing materials, how to collect data to report to CT DPH, and how to access additional resources and materials. The policy can be found in the Appendixes. For more information on self-testing visit: https://www.cdc.gov/hiv/basics/hiv-testing/hiv-self-tests.html.

INSTI Tests

INSTI test is another brand of HIV test that frontline can use when conducting rapid testing in their office or out in the field. INSTI is the fastest HIV test which delivers accurate results in as little as one minute. As most clients may be pressed for time, this option will help alleviate the 20-minute processing time, allowing for more time to provide resources to your client and link them into care. The INSTI test detect the IgM antibodies which are produced by the body in response to exposure to HIV and become detectable about 21 days post-infection. Unlike the OraQuick test however, the INSTI test requires a fingerstick and a drop of blood.

Agencies are encouraged to discuss the option to use INSTI tests with their Contract Manager. For more information on INSTI tests, use this link: https://www.insti.com/

Testing Algorithms

Most HIV testing conducted in nonclinical settings will include an initial HIV test and, if the initial HIV test is reactive, a follow-up HIV test. If follow-up testing is required, both the initial and follow-up tests are considered part of the same testing event for reporting purposes for CDC-funded programs.

An initial HIV test will either be an antibody test or combination antigen/antibody test. It may involve sending blood to a laboratory or obtaining blood or oral fluid for a rapid test.

Follow-up testing (sometimes referred to as "supplemental testing" or "confirmatory testing") is performed if the initial test result is positive. HIV tests are generally very accurate, but follow-up testing is important to be sure of the diagnosis of HIV infection.

Laboratory Testing Algorithm

In 2014, CDC published new recommendations for the HIV testing algorithm in laboratory settings (http://www.cdc.gov/hiv/pdf/HIVtestingAlgorithmRecommendation-Final.pdf). The updated recommendations outline a new testing algorithm that begins with a combination antigen/antibody test that detects both HIV-1 and HIV-2 antibodies. This algorithm has many advantages over previous ones:

- follow-up testing does not rely on the Western blot, which does not detect early infections
- accurate diagnosis of HIV-2
- potential for earlier diagnosis of HIV-1

Note: The recommended HIV testing algorithm cannot be used with oral fluid specimens.

Point-of-Care Testing Algorithm

Unlike laboratory testing, CDC has no published guidelines for point-of-care testing algorithms. However, the CT DPH has determined a point-of-care algorithm believed to be the most effective.

Point-of-care rapid HIV testing should follow one of the two testing algorithms determining if staff is trained and able to draw a blood sample:

1. Single rapid test with immediate linkage to clinical provider if initial test is reactive; if initial test is nonreactive, client is presumed to be HIV-negative and linked into PrEP Services.
2. Single rapid test followed by laboratory-based follow-up testing if initial test is reactive and a blood sample can be collected; if initial test is nonreactive, client is presumed to be HIV-negative and linked to PrEP Services.

Agencies should refer to their Contract Manager should they have any questions or concerns.

Specimen Collection and Preparation

Regardless of the HIV testing method you are using, you should perform specimen collection and preparation correctly and consistently to ensure the accuracy of your clients' test results. All HIV testing providers should be trained in the specimen collection procedure that is used at their agency—whether venipuncture, fingerstick, or oral fluid. Practical hands-on training should be available through your local health department. CDC's Rapid HIV Testing Online Course also provides some of this information, and can be accessed at http://effectiveinterventions.cdc.gov/en/HighImpactPrevention/PublicHealthStrategies/CTR.aspx.

Every test kit also has a product insert, which should be readily available to all persons conducting the HIV test. This insert should be consulted to ensure accurate procedures. However, although job aids such as the test kit insert are helpful, they should not be relied on as the sole source of information for conducting tests. All agencies should have HIV testing policies and procedures that describe instructions for accurate specimen collection and preparation, as well as safety precautions and a biohazard disposal protocol to protect clients and testing personnel.

Interpreting Results

In order to deliver an accurate message about the meaning of HIV test results, you should be familiar with the testing algorithm used by your agency. Remember to use simple and clear language to explain test results to clients. We provide examples of this language for each type of result below.

Laboratory-Based Testing

Reactive Results: If the results from the CDC-recommended laboratory algorithm or an algorithm using oral fluid in the laboratory indicate HIV infection, clients should be linked to HIV medical care and referred to partner services (PS) and/or other prevention services. If the laboratory algorithm results indicate an acute infection, linkage to care should be expedited, if possible, due to the increased risk of transmission to partners. In addition, it is beneficial for clients to be counseled to assist them in adopting risk-reduction strategies.

Nonreactive Results: A nonreactive test result indicates no evidence of HIV infection and can be interpreted as HIV negative. Depending on the window period associated with the test that you are using, clients that report recent known or possible exposure to HIV can be advised that, because of their recent exposure, it is possible the test did not detect HIV antibodies at this time. You should recommend retesting at an appropriate interval based on the client's risk and the type of test used. Chapter 5 elaborates on retesting recommendations.

Indeterminate Results: On occasion, testing with the Western blot or other follow-up antibody tests will yield indeterminate results. These test results may be related to recent infection, infection with HIV-2, concurrent infection with other viruses or diseases, vaccination (e.g., HIV vaccine trial participants), or problems with the sample or testing procedure. In this case, laboratories should conduct a NAT to rule out the possibility of acute HIV-1 infection. Sometimes, the laboratory may request an additional specimen to conduct the NAT. If the laboratory used by

your agency cannot perform a NAT, the client must be referred for follow-up testing that includes a NAT.

CLIA-Waived Rapid HIV Testing

Reactive Initial Results: If the initial rapid HIV test is reactive, this indicates that HIV antibodies or antigen have been detected. The result is interpreted as a *preliminary positive* test result and follow-up testing is required to confirm the diagnosis. In most cases, clients who are reactive on their initial rapid HIV test are *true positives*; that is, they are likely to be reactive on a follow-up test as well and should be prepared to receive a confirmed positive result. For this reason, it may be beneficial to immediately link clients who have *preliminary positive* test results to HIV medical care and to PS if follow-up testing cannot be conducted onsite. It is also important to counsel clients and to assist them with risk-reduction strategies while they wait for their follow-up test results.

Follow-up testing should be arranged according to the algorithm your agency uses for rapid testing, which might include 1 of 2 possible options:

1. Make a referral to a clinical provider that can perform follow-up testing and immediate linkage with HIV medical care. The client may also return back to you to be linked with other services, as appropriate.

2. Collect a sample and send it to a laboratory for follow-up testing, and ask the client to return to you to receive their results and get linked with HIV medical care or other services, as appropriate.

Once you have the results of the follow-up test (whether received from a laboratory or from your second rapid HIV test conducted onsite), you should deliver these as confirmed results. In most cases the results of the follow-up test will match the results of the initial test; that is, they will also be reactive, and you will confirm the client's HIV-positive status.

In rare cases, an initial rapid HIV test will be reactive, and a follow-up test will be nonreactive. If this happens when follow-up testing is done at a clinical provider or laboratory, it will either be resolved before your agency receives the follow-up test results, or your agency should receive guidance about how to deliver these results and the next steps. However, if this happens when you are conducting a second rapid HIV test onsite, you may need to incorporate language about what this means and what the next steps are.

Nonreactive Results: If the result of a rapid test is nonreactive, the test result is interpreted as HIV-negative. Depending on the window period associated with the test that you are using, clients that report recent known or possible exposure to HIV can be advised that, because of their recent exposure, it is possible the test did not detect HIV antibodies at this time. You should recommend retesting at an appropriate interval based on the client's risk and the type of test used. Chapter 5 elaborates on retesting recommendations.

Invalid Results: If a rapid test produces an invalid result, it cannot be interpreted. Invalid results are often the result of user error, which means you may have conducted the test incorrectly. You should repeat the HIV test on a new sample obtained from the client and may wish to call in a

supervisor or other experienced HIV testing provider to assist with the test. For additional information on invalid rapid test results, refer to the package insert provided with the test kit by the manufacturer.

Cautions Regarding the Window Period and Acute Infection

In an attempt to address the window period, many agencies recommend that HIV-negative clients return for retesting 3 months after a potential exposure to HIV in order to feel more confident with their results. However, if this message is given to all clients regardless of their specific risk, this message can be diluted, and clients may not fully understand the importance of identifying acute HIV infection. Furthermore, many clients may interpret this message as "3 months from their last HIV negative test," prolonging the time until they are retested and potentially missing opportunities for identifying acute infection.

If someone has acute HIV infection, they can be highly infectious and may be likely to transmit the virus to others. Clients should understand the importance of identifying HIV infection as early as possible. If a client is concerned about a recent exposure or they report symptoms of acute HIV infection such as persistent fever, swollen throat or lymph nodes, or other severe flu-like symptoms, they should be referred immediately to their doctor or other local clinic for acute infection testing. You should emphasize the need for using protection until acute infection can be ruled out. If testing immediately for acute infection is not an option, then the client should be tested at your site and then retested 3 months after their potential exposure.

False-Negative Test Results

False-negative test results occur when someone who is infected with HIV receives an HIV-negative test result. This scenario has been documented in persons on ART43 and in some persons receiving PrEP.44 However, additional data are needed to determine the extent to which test performance is affected by these factors. HIV testing providers may wish to ask clients if they are currently using ART, nPEP/PEP, or PrEP, in order to determine if additional testing is necessary to rule out a false negative result. False-negative results may occur for other reasons as well, such as test design, improper test procedures, or mislabeling of the specimen.

False-Positive Test Results

False-positive test results occur when someone who is not infected with HIV receives an HIV-positive test result. This scenario is not frequent but can occur in clients who are participating in HIV vaccine trials. HIV vaccine-induced antibodies can cause a rapid HIV antibody test to give a positive result, even though the person does not have HIV. All clients who receive an HIV-positive test result and who are also HIV vaccine trial participants should contact the vaccine trial site for evaluation or to receive a referral to HIV medical care for further evaluation and/or testing.

False-positive test results also occur in people who have not received the HIV vaccine in the study trial. The number of clients who received false positive test results will vary based on the type of tests you use and the HIV prevalence in your setting.

False-positive results may also occur for other reasons such as those mentioned under false-negative results.

Delivering Test Results

Your agency should have clearly defined protocols for delivery of HIV test results. These protocols can be described in your agency's HIV testing policies and procedures. Although there are pros and cons to the different approaches for delivering HIV test results, (e.g., face-to-face, telephone, or Internet), it is most important that clients do receive their results, as well as referrals to and linkage with appropriate follow-up services.

If you use laboratory testing as either the initial HIV test or for follow-up testing after a reactive rapid HIV test result, you will need to schedule a second encounter with the client in order to deliver their confirmed results. However, if rapid HIV testing is performed, the vast majority of clients will receive their test results on the same day during the testing encounter.

Face-to-Face Delivery

Delivering results face-to-face allows you to have some engagement with the client, to assess their reaction to their test results, and to link them with HIV medical care or prevention services, if indicated, or to other appropriate follow-up services. For most nonclinical sites conducting rapid HIV testing, results can be delivered face-to-face during the same visit at which the client was tested. If laboratory testing was conducted, you may still wish to schedule a return visit for the client to deliver their results face-to-face at your site. When possible, it is recommended that HIV-positive results be delivered face-to-face.

Telephone or Internet Delivery

At times, agencies use telephone or Internet (email, video chat, or other secure messaging service) to deliver a client's HIV test results. This approach may be beneficial for clients who are not likely to return to the testing site for their results. Although this approach is not ideal for delivering HIV-positive test results, if it is the only way a client will receive their results, then it should be supported. Agencies who deliver results by telephone or Internet should make a concerted effort to ensure clients have all the information and support they need to access HIV medical care or prevention services, as indicated, and other appropriate follow-up services. Some agencies have had success with video chat for returning results, since it allows for some personal engagement of the client. This can be particularly useful for agencies supporting home-based HIV testing, for following up with clients and supporting linkage to care, as appropriate.

Written Results

Clients sometimes request written copies of their test results. If you are delivering written HIV-negative test results, the results should be accompanied by a clear statement about the meaning of the test results, relative to the window period of the test used. It may also be useful to indicate when the client should return for retesting. If your agency is providing written test results they should be provided on your agency letterhead or a similar form and should clearly state the following:

- The name of your agency and the date the test was conducted
- The test result (positive or negative)

- Explanation of the result relative to the window period and/or date for retesting

Written results should not be provided when conducting anonymous HIV testing. It is important to address provision of written test results in your agency's policies and procedures.

Integration of Hepatitis Services

Due to the fact that Hepatitis C (HCV) can be transmitted in the same way as HIV and the high prevalence of HCV among injecting drug users, DPH has established protocol for incorporating HCV prevention counseling into the HIV prevention counseling session. In order to integrate Hepatitis C (HCV) counseling into the pretest counseling session questions should also be asked regarding transfusions, blood product receipt and organ transplant prior to 1992 as well as receipt of clotting factor concentrates prior to 1987.

Agencies funded to conduct HIV testing will also have access to HCV test kits. The counselor should ask if the client has ever been tested for HCV and if they would like to be.

Since the HIV and HCV rapid tests are both conducted using fingerstick blood, gathering the necessary sample can be done at the same time. Be sure to prepare the testing site for both tests prior to gathering the blood sample, as you would normally for the HIV rapid test.

Should the client have a reactive HCV test, the same referral protocol needs to take place by linking the client to the proper support services to have a confirmatory test done and follow-up treatment if needed.

Hepatitis A and B Vaccinations

The State Department of Public Health (CT DPH) is committed to increase Viral Hepatitis education, prevention, testing, linkage to care and treatment, and increase vaccination for Hepatitis A and B. CT DPH aim is to continue to build and sustain relationship with partners in high-impact settings for the expansion of integrated services to address one or more of the intersecting epidemics.
As of April 2020, the Centers for Disease Control and Prevention (CDC) recommends that primary care providers conducts universal screening for all adults 18 years and older at least once in their lifetime for hepatitis C; hepatitis C screening for all pregnant women during each pregnancy; and one-time hepatitis C screening regardless of age or setting prevalence among people with recognized conditions or exposures; routine periodic testing for people with ongoing risk factors such as people with HIV and among People Who Use Drugs (PWUDs); and, screen any person who requests hepatitis C testing. Since Hepatitis C (HCV) can be transmitted in the same way as HIV and with the high prevalence of HCV among PWUDs, DPH has established protocol for incorporating HCV prevention counseling, and education, and referral for vaccination for Hepatitis A and B, into the HIV prevention counseling session. To integrate Hepatitis C (HCV) counseling into the pretest counseling session questions should also be asked regarding HIV status, pregnancy status, blood transfusions, blood product receipt and organ transplant prior to 1992 as well as receipt of clotting factor concentrates prior to 1987.

Around 62-80% of injection drug users with HIV also have Hep C. Having both HIV and Hepatitis C more than triples the odds for liver disease, liver failure, and liver-related death. This means testing is even more important for those at risk for both HIV and Hep C – and testing is easy! There are no vaccines for HCV but there are vaccines for HAV and HAB. Hepatitis C can be treated

and can be cured. Over 90% of people with Hep C are cured with just 8-12weeks of treatment. Hep C cures are covered by most Medicaid and Medicare policies, and major private insurers.

Agencies funded to conduct HIV testing will also have access to HCV test kits. To increase routine HCV and HBV testing in funded health systems and Routine Testing Sites (RTS), the counselor should ask if the client has ever been tested for HCV and HBV, or if they have ever been vaccinated for HAV and HAB and if they would like to be. Since the HIV and HCV rapid tests are both conducted using fingerstick blood samples, gathering the necessary sample can be done at the same time. Be sure to prepare the testing site for both tests prior to gathering the blood sample, as you would normally for the HIV rapid test. Should the client have a reactive HCV test, the same referral protocol needs to take place by linking the client to the proper support services to have a confirmatory test done and follow-up treatment if needed. Please see the CT DPH HIV/HCV Reporting Guidance for information in reporting positive HCV results.

To prevent an outbreak of Hepatitis A Virus (HAV) infections among persons who use drugs and persons experiencing homelessness Health care providers are encouraged to vaccinate all persons at high risk including persons experiencing homelessness, persons who use injection or non-injection drugs or have chronic liver disease (including chronic hepatitis C infection or chronic hepatitis B infection), and men who have sex with men. If your site does not provide vaccine, The Connecticut Vaccine Program (CVP) does provide the following adult vaccines for **uninsured HIV adults** in CBO's: Tdap (Boostrix)-ages 19 and older; Hepatitis A (Havrix)-ages 19 and older; Hepatitis B (Heplisav-B)-ages 19 and older; Hep A/Hep B combination (Twinrix)-ages 19 and older. Attached is the link to begin the enrollment process: https://portal.ct.gov/DPH/Immunizations/CVP--Provider-Profile-Enrollment_Reenrollment

Hepatitis A can be prevented. The HAV vaccine is the best protection. The following are recommended to be vaccinated: Travelers to countries with increased rates of hepatitis A; men who have sex with men; Injecting drug users; Persons with chronic liver disease; Persons with clotting factor disorders (such as hemophilia)

Please see the CT DPH HAV Advisory and the CT DPH Hepatitis B Protocol

Conducting HIV Testing with Individuals

All HIV testing sessions in nonclinical settings will generally follow the same overall structure, regardless of where they are being conducted or who is being tested. That is, you will conduct certain steps before delivering the results (called "pre-results steps"), and certain steps after delivering results (called "post-results steps"). This chapter will review these steps, outline essential tasks for each step, and present additional considerations for your HIV testing session with individual clients.

Reduced Counseling Approach

For individual HIV testing, CDC no longer supports extensive pretest and posttest counseling. Instead, HIV testing providers should conduct brief, information-based sessions tailored to their clients, as outlined below. CDC has found this strategy to be more effective in a rapid HIV testing environment.

The most widely recommended intervention pairing HIV prevention counseling and HIV testing, Project RESPECT, was originally conceived as involving traditional HIV tests that required clients to return for their test results several days after testing. Because of the changed HIV testing environment, CDC no longer supports the RESPECT intervention or the HIV prevention counseling protocol that is based on the RESPECT model.

For couples that are tested together for HIV, the "Testing Together" protocol does include brief counseling in order to establish rapport with the couple as a unit and enhance their ability to communicate about their joint HIV risk concerns. However, this approach can also be done rapidly and follows the same "pre-results steps" and "post-results steps" formats, which are described in the next chapter (Conducting HIV Tests with Couples).

6 Steps for Conducting HIV Tests with Individuals

The steps for individual HIV testing will vary slightly depending on the type of test kit and testing algorithm that is being used. Presented are the steps for the 20-minute rapid test scenario. The steps for the 1-minute INSTI rapid test scenario can be found following the 20-minute scenario.

20-Minute Rapid Test Scenario

Step 1: Introduce and orient the client to the session

Step 2: Prepare for and conduct the rapid HIV test

Step 3: Conduct brief risk screening

Step 4: Deliver results

Step 5: Develop a care, treatment, and prevention plan based on results

Step 6: Refer and link with medical care, social and behavioral services

The first 3 steps are pre-result steps for individual HIV testing and the last 3 are post-result.

Pre-result Steps:

Step 1: Introduce and Orient the Client to the Session

The first thing you will do when conducting an individual HIV testing session is introduce yourself and orient the client to the session. The key tasks for step 1 are:

- Introduce yourself and describe your role
- Provide a brief session overview, including:
    - How long the session will take
    - Process for conducting the test
    - How results are returned (i.e., same day or return for results)
- Collect pertinent client information, including contact and locating information. (See Appendix section for reporting guidance, including forms)
- Obtain concurrence to proceed with the session

This step is important for building rapport and establishing client expectations for what will happen during the HIV testing session. Generally, this step will take about 1–2 minutes.

Step 2: Prepare for and Conduct Rapid HIV Test

In step 2, you will provide the client with basic information about the HIV test. Use simple, clear language that the client can understand. Provide information in a language and at a reading level appropriate to the client. Information can be presented verbally, written, or through videos, computers, or other electronic technology. It should take approximately 1–2 minutes to provide the client with this basic information and answer any questions he or she might have about the rapid testing process. Then you will collect the sample and conduct the rapid HIV test. The key tasks for step 2 are:

- Explain the process of conducting the HIV test, including:
    - Type of test used (rapid vs. non-rapid; antibody vs. combination antibody/antigen test)
    - Sample collected (blood vs. oral)
    - Time until test results are ready
- Explain the meaning of HIV-negative and HIV-positive test results, including:
    - Need for retesting if HIV-negative
    - Need for and process of conducting follow-up testing if HIV-positive
    - Possibility of invalid result
- Obtain consent to test (oral or written)
- Distribute test kit information booklet (required for CLIA-waived tests)
- Collect specimen and conduct rapid HIV test

If you conduct the test in the same room where the session occurs, it is suggested to set the test kits to the side while they are developing, or set up a screen to block the client's view so that the client does not get distracted or anxious watching the test develop. If the test is conducted in an onsite laboratory—or, in the case of mobile or outreach testing, in a central location where one person is responsible for doing multiple tests—you must ensure client confidentiality and accuracy of test results. Tests should always be performed according to the directions outlined in the test kit insert, and test kits should be clearly labeled to ensure that the correct results are given to the correct client.

Step 3: Conduct Brief Risk Screening

While you are waiting for the test results, take a few moments to conduct brief risk screening to better understand the client's HIV risk. You may use your agency's data collection tools to guide the risk screening, or you may engage the client in a brief discussion of their immediate risk concerns. You may start by asking the client how they decided to be tested, and then listening and probing for additional information about immediate, recent, or ongoing risk. If the client needs to be referred immediately for other services such as nPEP, acute infection testing, or medical care, make linkages with those services at this point. Use the information clients tell you to prepare them for their possible results, and tailor recommendations after you deliver their results.

The timing of step 3 will vary greatly depending on the HIV risk concerns of the client. This step should be conducted in 5-10 minutes. The key tasks for step 3 are:

- Ask how the client decided to be tested; listen and probe for previous testing history and indicators of increased risk including:
    - Potential exposure in last 24–72 hours *(to indicate need for nPEP)*
    - Potential exposure in last 3 months *(to indicate need for acute infection testing)*
    - Symptoms *(to indicate need for acute infection testing and accessing medical care)*
    - Ongoing risk behavior or key population (MSM, PWID, partner with unknown or known HIV-positive status, transgender woman)
- Address indicators of increased risk and make immediate referrals to other services (i.e. nPEP, acute infection testing, or medical care) as indicated
- Assess the client's knowledge of HIV transmission, provide accurate information as needed
- Prepare for possible test results

As you conduct the brief risk screening, your client may have questions about acute infection, the window period, and retesting for HIV, which can also be addressed while you are waiting for the test results.

Testing frequency

CDC recommends that all adolescents and adults get tested at least once for HIV as a routine part of medical care, and that MSM and others at high risk for HIV infection be tested at least annually. In addition, MSM and other high risk individuals might benefit from more frequent screening, such as every 3 to 6 months.

Post-results Steps:

The 3 post-results steps for individual HIV testing are:

Step 4: Deliver results

Step 5: Develop a care, treatment, and prevention plan based on results

Step 6: Refer and link with medical care, social and behavioral services

If you are conducting laboratory testing, remember that you will include 1 additional step before delivering results. When the client returns to your site for his or her result (ideally no more than 1 week after the initial visit), you should first take a moment to check in with the client to address any HIV risk concerns or issues since the last visit. Then proceed with delivering results.

Step 4: Delivering results

Step 4 is the delivery of results.

If you are conducting a CLIA-waived rapid HIV test, after following the manufacturer's instructions and allowing for the appropriate time for the test to process, you will read the test device and interpret the result. If the test was conducted by another staff at your agency or outside the room where the client is waiting, obtain the result and return to the client. If the client was in the waiting room, call him or her back to the HIV testing room to receive their result. If the test result is preliminary and must be confirmed with a follow-up test, you will indicate this to the client and follow your agency's procedures (as outlined above) for follow-up testing.

The 2 key steps for delivering results are:

- Confirm the client's readiness to receive their result
- Provide a clear explanation of the client's result

Most clients will confirm that they are ready to receive their result because they came to you specifically for this purpose. Their confirmation is also an indication that you have done a successful job preparing them to receive their result during the pre-results steps.

On very rare occasions, clients may change their mind about receiving their result. If clients state that they are not ready to hear their result, engage them in a discussion about reasons they do not feel ready. Provide motivation and support for clients by reminding them of the importance of knowing their status and making decisions for their health based on their status. Once the client has a chance to talk about his or her concerns, they may be ready to hear their result. If

the client still refuses, respect his or her decision, discuss options for getting the result at a later date, and make arrangements to follow-up with the client.

Step 5: Develop a Care, Treatment, and Prevention Plan Based on Results

Step 5 is to develop a care, treatment, and prevention plan with the client based on their HIV test results and risk issues identified during the brief risk screening. After receiving their test result, whether HIV-negative or HIV-positive, clients may have a hard time absorbing lots of information so it may be most effective to identify key referral services, make linkages with those services, and schedule follow-up visits if the client has additional concerns. Alternatively, another provider, such as a linkage coordinator or patient navigator, can also address the client's concerns during follow-up visits.

The overall flow of step 5 should be similar for clients who receive an HIV-negative or HIV-positive test result, but the specific tasks will be different based on their result. The tasks will also vary slightly depending on your agency's process for conducting follow-up testing for clients with an initial reactive rapid HIV test.

HIV-Negative Clients

For clients testing *HIV-negative*, the specific tasks for step 5 are:

- Explore client's reaction to result
- Discuss need for retesting based on window period of test used and client's risk
- Emphasize key risk reduction strategies that will help the client remain HIV-negative:
    - Choose less risky sexual behaviors
    - Get tested for HIV together with partner(s)
    - Use condoms consistently and correctly
    - Reduce number of sex partners
    - Talk to doctor about PrEP (as indicated, according to PrEP screening indicators)
    - Talk to doctor about nPEP (as indicated, within 3 days following a specific exposure to HIV)
    - Get tested and treated for other STDs and encourage partners to do the same
    - If partner is HIV-positive, encourage partner to get and stay on treatment
- Provide condoms

Clients receiving an HIV-negative test result may experience a range of emotions, including relief, shock, joy, or dismay. HIV testing providers should be prepared for any number of responses from clients and should remain neutral as they explore the client's reaction.

It is important to reinforce HIV prevention messages, to motivate the client to remain HIV-negative, and support them to access medical, social, and behavioral referral services, as indicated based on their risk and specific situation.

Indications for PrEP

As the first point of contact for many high-risk HIV negative clients, HIV testing providers in nonclinical settings should not only educate clients about PrEP, but they should also know and assess for PrEP indications and refer persons at substantial risk for acquiring HIV to a PrEP counselor or medical provider where PrEP is available. PrEP providers will conduct additional risk behavior assessments or use a risk index to determine if clients are appropriate for PrEP.

The criteria that HIV testing providers use to determine whether HIV-negative clients are at substantial risk of acquiring HIV and should be offered PrEP may be assessed over the course of the client's HIV testing session or at the end of the session after you have delivered their results. This is considered an important part of revisiting the risk discussion and reinforcing decisions that will help the client remain HIV-negative. PrEP is currently indicated for MSM at substantial risk of HIV acquisition, as well as heterosexual men and women and PWID at substantial risk of HIV acquisition. This may include persons who have unprotected sex or inject drugs with multiple partners of unknown HIV status, or persons who are in known HIV-discordant relationships, where one partner is HIV-negative and the other partner is HIV-positive.

HIV-Reactive Clients

For clients who test *HIV-reactive*, the specific tasks for step 5 are:

- Explore client's reaction to result
- Advise on next steps for follow-up testing
- Discuss disclosure and inform about processes for partner services
- Advise to access care and treatment for HIV
    - Treatment can help people with HIV live long, healthy lives and prevent transmission
    - Other health issues can be addressed
- Emphasize key risk reduction strategies that will prevent transmission
    - Choose less risky sexual and drug-using behaviors
    - Get tested together with their partners
    - Use condoms consistently and correctly
    - Reduce number of sex partners
    - Encourage partners to be tested
- Provide condoms

Clients receiving an HIV-positive result for the first time might also experience a wide range of emotions, including shock, grief, or other strong feelings. While exploring the client's reaction to his or her result, you can effectively use silence to express empathy and give the client space to absorb this new information. Attend to the client's immediate needs before moving on with the other tasks.

Advise the client on their next steps for follow-up testing to confirm the HIV-positive test result. Follow-up testing can be addressed in a number of ways:

1. Immediately link clients to medical care for follow-up testing after the initial reactive rapid test result.
2. Collect a specimen to send to a lab for follow-up testing after the initial reactive rapid test result; discuss the importance of returning to the agency to get the test result; and schedule a day and time for the client to return to the agency to get the result of the follow-up test.
3. Collect a specimen and run a second rapid test using a different rapid test to confirm the result (see Chapter 4 for additional information, including suggested language for what to do if the second test is also reactive, which is to proceed with steps 5 and 6, versus a nonreactive result, which is to refer the client to a clinical provider or collect a sample to send to the laboratory).

Although it might be difficult in this moment for clients to grasp everything you are telling them, it is important to discuss disclosure to sex partners, inform them about the processes for partner services and to reinforce the importance of accessing care and treatment. Most clients will be referred for follow-up testing to confirm their result and to be enrolled in HIV medical care, so that they can begin accessing treatment as soon as possible to prevent transmission and help them stay healthy.

Remember that this is not the last encounter clients will have with the health care system, your primary goal should be to link clients with medical care and other necessary follow-up services—either directly or through a patient navigator or linkage counselor—as discussed in the next step.

Step 6: Refer and Link with Medical Care, Social, and Behavioral Services

Throughout the HIV testing session, you will receive information from clients that will help you determine what additional services they need in order to stay healthy, safe, and prevent HIV transmission or acquisition. Before you close the session, you will identify the necessary medical, social, and behavioral services that are appropriate for the client, and then provide the client with referrals and link them to these services. Some of these services may be provided by your agency; for others, you will need to refer outside your agency.

The 3 tasks for step 6 are:

1. Identify necessary medical, social, and behavioral referral services
2. Make referrals as indicated
3. Track linkage to HIV medical care

For clients who test HIV-negative, some of the services you might refer them to include:

- nPEP
- PrEP

- Partner or Couples HIV testing
- Retesting for HIV
- Screening and treatment for STDs, hepatitis, and/or TB
- High-impact behavioral interventions that can reduce their risk of acquiring HIV
- Reproductive health services
- Counseling and services for mental health, substance abuse, and/or domestic violence
- Insurance navigation and enrollment
- Housing
- Other social and behavioral services

For clients who test HIV-positive, some of the services you might refer them to include:

- HIV care and treatment
- Partner services
- Medication adherence services
- Partner or Couples HIV testing
- Screening and treatment for STDs, hepatitis, and/or TB
- High-impact behavioral interventions for newly diagnosed HIV-positive persons
- Reproductive health services
- Counseling and services for mental health, substance abuse and/or domestic violence
- Insurance navigation and enrollment
- Housing
- Other social and behavioral services

1-Minute INSTI Test Scenario

The INSTI test scenario only slightly differs from the 20-minute version in that the risk screening needs to happen prior to conducting the test. Being that the INSTI test has a processing time of only 1 minute, the tester will require more time to access the client's level of risk to determine their candidacy for PrEP.

The following are steps for the 1-minute INSTI test:

Step 1: Introduce and orient the client to the session

Step 2: Prepare for INSTI HIV test and conduct brief risk screening

Step 3: Conduct the HIV test

Step 4: Deliver results

Step 5: Develop a care, treatment, and prevention plan based on results

Step 6: Refer and link with medical care, social and behavioral services

Partner Services

PS is implemented with all persons who test HIV-positive. The primary function of PS is to notify the sex and drug-injecting partners of HIV-positive individuals about their potential exposure to HIV. It is a voluntary service that involves interviewing newly diagnosed HIV-positive persons to elicit names of their previous sex and drug-injecting partners who might have been exposed to HIV, then confidentially notifying these persons of their potential exposure and offering them HIV testing and linkage to HIV medical care, social, and behavioral services. Local health departments play a key role in implementing PS, and nonclinical HIV testing providers should be aware of the PS protocol followed by their agency.

Examples of partner services protocols include:

1. **Refer to local health department**—persons newly diagnosed with HIV are referred to the local health department where a Disease Intervention Specialist (DIS) conducts an interview to elicit the names and locating information of previous partners who may have been exposed to HIV. The DIS then contacts these partners and offers them HIV testing. In some jurisdictions, the health department initiates PS automatically when it receives an HIV case report form. Clients should be informed that the health department will contact them to discuss PS.

2. **DIS onsite**—some agencies have health department DIS staff onsite to interview clients who test HIV-positive.

3. **DIS on call**—some agencies work with the local health department to have DIS staff on call. When an individual is newly diagnosed with HIV, the DIS can be contacted and can arrive quickly at the agency to interview the client.

4. **CBO elicitation**—some CBOs have authorization from the health department to interview newly diagnosed clients and elicit their partner names and locating information. This information is provided to the health department to locate and notify partners of their potential exposure to HIV and provide HIV testing.

Referral to clinical provider for follow-up testing

If your agency refers to a clinical provider immediately following an initial rapid reactive HIV test, confirmatory testing will be done by the clinical provider.

Send sample to offsite laboratory for follow-up testing

If, following an initial rapid reactive HIV test, your agency collects a sample from the client and sends this to an offsite laboratory for follow-up testing, you will need to schedule a second visit with the client to return their confirmed results. Ideally these results should be returned no more than 1 week from the initial testing date.

Following the initial reactive HIV test result, you should still proceed with steps 4–6, you will just tailor these to the client's situation and the reality of the initial HIV test results. For example, you will still provide information about HIV care, treatment, and prevention, but you will indicate that

these recommendations are based on the *preliminary positive* result, not the confirmed result. You will revisit these recommendations once you have the confirmed result.

Conducting Social Network Strategy

Social Networking Strategy (SNS) is a peer-driven approach to recruitment that involves identifying HIV- positive or high-risk HIV-negative persons from the community to serve as "recruiters" for your agency. Recruiters deliver key messages and encourage HIV testing among high-risk persons in their social, sexual, or drug-using networks. They may use coupons or invitations as a way of documenting that they have delivered these messages to potential clients. The recruiters are trained or "coached" on the best approaches to reach their peers, including who should be reached through this approach and what messages can motivate their peers to be tested for HIV. Partner referral is a type of social networking that involves recruiters referring their sexual partners to an HIV testing program. Recruiters may refer their sexual partners to be tested alone, or recruiters may accompany their partners and be tested together, as outlined in Chapter 6 on Couples HIV Testing and Counseling.

Conducting & Implementing SNS

The Social Network Strategy for HIV Testing Recruitment is conducted by completing ten various procedures. The procedures are as follows:

1. Community and Focus Population Engagement
2. Recruiter Enlistment
3. Recruiter Engagement
4. Recruitment of Network Associates
5. HIV Testing
6. Inviting Network Associate to Become Recruiters
7. Ensuring Confidentiality for Social Network Strategy for HIV Testing Recruitment
8. Potential Risks for Recruiters
9. Data Collection and Program Monitoring
10. Quality Assurance

For the complete Operating Procedures Manual, click the link below for a downloadable PDF.

Social Network Strategy Link:

HTTPS://WWW.CDC.GOV/HIV/EFFECTIVE-INTERVENTIONS/LIBRARY/SOCIAL-NETWORK-STRATEGY/IMPLEMENTATION-MATERIALS/CDC-HIV-EI-SNS-STANDARD-OPERATING-PROCEDURES.PDF

Conducting Testing Together

Couples HIV testing and counseling (CHTC), or *Testing Together*, is an approach to HIV testing, whereby two or more persons who are in—or are planning to be in—a sexual relationship are tested for HIV together. Couples go through the entire process together and receive their results together. Testing Together is different from individual testing because it is not focused on past risk behavior, but rather supports couples to address their joint risk concerns with a focus on the present and the future. Couples are only separated if there is suspicion of coercion or to confirm information collected on individual data forms. Testing Together is voluntary, and couples may decide at any time during the session that they prefer to be tested separately.

Differences from Individual Testing

Testing Together follows a very similar structure to individual HIV testing but with some key differences.

Comparing Individual HIV Testing with Testing Together

Individual HIV testing	Testing Together
Clients learn their individual HIV status alone.	Clients learn their own HIV status as well as that of their partner(s).
Clients must disclose to their partner on their own, or use PS.	Counselor-facilitated mutual disclosure among partners is immediate and 100%.
Clients deal with issues of tension and blame on their own.	Provider is there to help ease tension and diffuse blame.
Individual risk screening is based on past risk behavior.	Couple's joint risk concerns are discussed with a focus on the present and the future.
Focus is on health education.	Skill building is focused on couple's communication and sexual agreements.
Referrals and linkage are based only on client's HIV status and needs.	Referrals and linkage are tailored to the results and needs of both partners.

Steps for Conducting Testing Together

The protocol for Testing Together looks very similar to the steps for conducting individual HIV testing. Compared to individual testing, which uses a very streamlined approach with minimal counseling, Testing Together may require brief counseling in order to establish rapport and enhance their communication as a couple. Similar to individual testing, the format includes "pre-results steps" and "post-results steps".

Rapid HIV Testing Together (20-minute read time)

Pre-Results Steps

Step 1: Introduce Testing Together and obtain concurrence

Step 2: Prepare for and conduct rapid HIV test (20-minute read time)

Step 3: Explore couple's relationship

Step 4: Discuss HIV risk concerns and reasons for seeking testing together

Step 5: Discuss couple's agreement

Post-Results Steps

Step 6: Provide results of initial rapid HIVB test and follow your agency's protocol for conducting follow-up confirmatory testing

Step 7: Develop care, treatment, and prevention plan based on results

Step 8: Refer and link with medical care, social and behavioral services

Just like with individual testing, the HIV test is conducted as step 2. Just as with individual testing, this list does not represent what to do if the results of the initial rapid are reactive. If your agency refers to a clinical provider immediately following an initial rapid reactive HIV test, confirmatory testing will be done by the clinical provider. If you send a sample to an offsite laboratory for follow-up testing after an initial rapid reactive HIV test, you would collect that sample after step 6 and return the confirmed results in a separate session, again ideally scheduled no more than 1 week after the initial visit. You will still proceed with steps 6–8, but you will tailor these to the couple's situation. If your agency conducts a second rapid HIV test onsite, you can perform this test immediately following delivery of the initial reactive HIV test result in step 6.

Implementing Testing Together

HIV testing providers must be trained in this approach before offering Testing Together services. In the training, providers learn the specific tasks that should be conducted for each step of the Testing Together protocol and practice skills-building exercises around couple's communication, self-awareness, sexual agreements, and discordant test results. There are also opportunities to practice delivering the steps of the Testing Together protocol through role plays. Because of the additional skills required for providing high-quality Testing Together services, it is recommended that HIV testing providers have provided individual HIV testing for at least 6 months or to at least 50 individual clients before receiving Testing Together training.

The same resources that are used for individual HIV testing can, and should, be used to offer Testing Together. All of the information in this Implementation Guide applies to both individual and couples testing, including the need to adhere to program principles and standards, the need for monitoring and evaluating Testing Together service delivery, and the need for quality assurance to ensure high-quality service provision. Because Testing Together is a service agencies will need to revisit and revise their targeting and recruitment plans to include couples.

More information about Testing Together training and how to access technical assistance for implementation support at your agency is available at: https://effectiveinterventions.cdc.gov/. This site also hosts a Testing Together toolkit with implementation support materials including videos, marketing materials, manuals, and worksheets.

Referral, Linkage, and Navigation Services

A primary goal of HIV testing in nonclinical settings is to identify clients with undiagnosed HIV infection and link them to HIV medical care as soon as possible. Additionally, HIV testing providers may play a role in the reengagement of previously diagnosed HIV-positive persons who are not currently engaged in care. Referral and linkage to HIV care services and initiation of ART facilitate better health outcomes for HIV-infected persons and can help prevent HIV transmission. Furthermore, HIV-negative persons at substantial risk for HIV infection may also benefit from referral and linkage to care for PrEP, STD testing and treatment, or other information and HIV prevention support. Both HIV-positive and HIV-negative clients may benefit from referral and linkage to other health services, including social and behavioral services as outlined in Chapter 5, and may need assistance navigating the health system in order to access these services.

This chapter discusses referral processes, linkage outcomes, and navigation services, and describes the steps that HIV testing providers can take to facilitate successful referral and linkage to HIV medical care, social, and behavioral services for their clients.

In some nonclinical settings, HIV testing providers may conduct referral and linkage services and, in others, they will refer clients to a linkage navigator or other staff who has this designated role. Keep in mind that there are often multiple factors that influence a client's ability or willingness to accept or access referral services, and it is not always appropriate or recommended to address all of these factors at one time. Referral and linkage is a process. It will likely extend beyond the initial HIV testing session and may warrant multiple visits with the client after they receive their HIV test results. Although you will do your best to support and motivate clients to seek referral services, it is ultimately in their hands to accept these services. In order to effectively implement referral and linkage services, you should be aware of the available and relevant resources to support your clients' health. You should also build partnerships with other health care organizations and community agencies to get your clients the services and care they need.

Defining Referral, Linkage, and Navigation

Referral is the process by which you actively provide clients with information and assistance in accessing medical care, social, and behavioral services. The referral process includes conducting an initial assessment of the client's needs, identifying and prioritizing those needs based on this assessment, identifying barriers to accessing referral services, developing a plan for accessing referral services with the client, and facilitating his or her access to these referral services.

Linkage is the outcome verifying the successful completion of your referral by the client. Linkage includes following up with either clients or providers to confirm linkage and documenting the results. For example, when you confirm and document that a client made it to the first medical appointment within 30 days following the initial diagnosis, this is considered successful linkage.

Navigation is the overarching system that includes referral and linkage, but which may also extend beyond these steps to include continuous engagement with clients or patients to ensure they remain engaged in HIV medical care, social, and behavioral services for as long as necessary to support viral suppression and HIV prevention. HIV navigation services are intended to serve both clients living with HIV as well as HIV-negative individuals who are at risk of acquiring HIV.

The objectives of HIV navigation services are twofold: (1) to provide direct assistance to clients in accessing services, and (2) to support clients in building the knowledge and skills necessary to access and use the system on their own. This process may require contacting clients or patients on a regular basis to identify and address their barriers to staying engaged in care. Navigation often extends beyond the HIV testing encounter.

Linkage Staff and Navigators

In some agencies, HIV testing providers will also provide referrals and linkage, but in other agencies, specialized staff will be hired as navigators and dedicated to helping clients with this process. The training and development of navigators (e.g., community health workers, peer advocates, outreach workers, case coordinators) will help facilitate access to and retention in HIV medical care and social and behavioral services. Navigators are sometimes peers—persons living with HIV who have successfully accessed medical, risk reduction, and other services. Additionally, depending on an agency or region's existing systems and programs, navigation services may be performed by several staff members—not just a single person—who may offer assistance at various points along the HIV care continuum.

Implementing Referral, Linkage and Navigation Services

Regardless of whether a client is newly diagnosed with HIV infection, has been previously diagnosed, or is HIV-negative, the steps for referral, linkage, and navigation follow the same basic process:

1. **Identify and prioritize referral needs:** In collaboration with clients, identify what services are most important for keeping the client healthy and safe and for preventing HIV transmission or acquisition. Prioritize these services based on the client's situation and needs. It may not be possible or appropriate to address all of the client's referral needs at one time, so efforts should be focused on facilitating referrals to services that can have the greatest impact on the client's health and risk reduction.

2. **Develop a plan:** Elicit the client's strengths that can be used to implement the referral plan successfully. Furthermore, help the client identify challenges or barriers he or she might have in completing referrals and develop strategies to overcome these challenges. Together with the client, identify the methods you will use to facilitate a referral and help the client complete this referral. Work out a plan to help the client successfully and regularly access the necessary care and services.

3. **Facilitate access to services:** Provide clients with the information and support they need in order to access referrals. This includes supplying them with provider contact information, cost, hours of service, eligibility information, and processes and timelines for making appointments; help in deciphering insurance and financial information; and support for maintaining strong and ongoing communication with service providers. Scheduling appointments for or with clients, accompanying clients to appointments, providing transportation information and assistance, giving ongoing patient education

and motivation, and sending appointment reminders can significantly increase the chance of successful referrals. Also be sure to make referrals that are culturally appropriate with regard to age, gender, race, ethnicity, sexual orientation, and other factors.

4. **Confirm and document linkage:** After a designated period of time, confirm and document linkage to referral services by contacting the referral provider or the client to determine if they accessed these services. Obtain client feedback, if possible. If the client was not successfully linked, attempt to determine the reasons for this and provide additional assistance, if appropriate. If the client was successfully linked, document this in the client's file, chart, or referral log. Electronic tracking systems are used by many organizations to track and document linkage.

5. **Maintain contact with client to support navigation:** Once a client has been successfully linked with HIV medical care, social and behavioral services, it may be necessary to remain in contact with them to help them navigate the health care system and other services they might need. Navigation may include accompanying persons to medical appointments, sending reminders and encouraging messages, providing counseling support, and identifying persons who have dropped out of medical care and helping them get reengaged.

Referral, Linkage, and Navigation Strategies

Step 6 of the individual HIV testing protocol and step 8 in the HIV testing protocol for couples is to refer and link clients to HIV medical care and essential social and behavioral support services.

In order to get clients to these services, CDC supports a number of navigation strategies for helping agencies manage the referral and linkage process. You can learn more about how to access training and technical assistance for these strategies in Chapter #.

- Antiretroviral Treatment and Access to Services (ARTAS): ARTAS is for linking individuals who have recently been diagnosed with HIV to medical care. ARTAS consists of up to 5 sessions with a client within a 90-day period or until the client is successfully linked to HIV medical care, whichever comes first. A client may be transitioned to a medical case manager for longer-term assistance and support.
- HIV Navigation Services (HNS): A model for helping clients understand the entire range of services across the HIV care continuum, including services for high-risk HIV-negative individuals. It is important to ensure that HNS roles and services complement and do not duplicate existing services, programs, and staffing. HNS is not new but is a different way of addressing a longstanding challenge of helping clients stay engaged in care by addressing the myriad of issues that might keep them out of care.
- Linkage Case Management: Intensive, short-term assistance to facilitate entry into care. A linkage case manager helps clients to develop a personalized plan to acquire needed services.

- Medical Case Management: Ongoing coordination of medical services and follow-up of a client's medical treatments in order to engage and retain HIV-infected persons in medical care. Some HIV testing providers also operate medical case management programs, often at the same site where HIV testing is provided.
- Outreach and Peer Support: Linkage services provided by and for individuals living with HIV. Through one-on-one and/or group interactions, peers can play an integral role in recruiting HIV-positive persons into services, particularly individuals from hard-to-reach populations, clients who have been reluctant to enter into HIV medical care, or individuals who have left medical care.

Each facility should have a list of community resources available to help meet the needs of their clients, and providers should be familiar with these resources. It may be helpful for HIV testing agencies to establish memorandum of agreement (MOAs) with local referral agencies, to streamline the referral process, to ensure high standards of service delivery, and to hold agencies accountable. Client confidentiality or anonymity must be maintained when making referrals.

Documenting Referrals and Monitoring Linkage

Referrals and linkage should be offered to all clients based on their needs. Due to funding requirements and resource capacity, agencies may need to prioritize the linkages that they monitor. In line with agency procedures, linkages can be documented in a client's chart or in a centralized referral log. You may wish to collect the following information about each linkage:

- Date and time linkage was made
- Name of staff person linking the client
- Type of linkage service
- Name of linkage service provider
- Type of assistance and/or incentives provided to help the client complete the linkage
- Date linkage was successfully achieved, if applicable
- Reasons that linkage was not successfully achieved, if applicable (e.g., client feedback on challenges to accessing services or satisfaction with services)

If an authorization of release of information was necessary to determine if a client was successfully linked to services, place a copy of the authorization in the client chart. Agencies should regularly monitor data to evaluate the extent to which referral and linkage strategies are successful in linking clients with needed services. This ongoing assessment enables agencies to determine whether referral and linkage practices should be changed to better meet the needs of their clients.

Tracking Linkage to HIV Medical Care

It is particularly important to track linkages for HIV-positive clients to medical care, and HIV-negative clients to PrEP providers. Agencies should adhere to state and local requirements for tracking and reporting these linkages, which may include periodically reporting the proportion of HIV-positive clients linked to medical care who accessed their first appointment within 30 days.

Two main strategies for monitoring whether clients are successfully linked to follow-up services are (1) provider confirmation and (2) client self-report.

Provider Confirmation: Provider confirmation is the preferred method for confirming linkage. The medical provider is contacted by an HIV testing staff member and asked whether the client accessed services. The provider then confirms "yes" or "no". The provider should also report the date that he client accessed services, if applicable or discuss the reasons why the client hasn't yet come in. It is recommended that HIV testing sites authorize specific staff to track these linkages with medical providers. Likewise, clinics should also assign specific staff to confirm the client's linkage. In the case of linkage to medical care, a physician, clinical social worker, or nurse practitioner is the appropriate authorized party.

Client Self-Report: You may sometimes have ongoing contact or interactions with clients beyond the initial HIV testing event. The next contact with a client after he or she is linked to services provides a good opportunity for asking the client whether he or she successfully accessed the service. This also provides a good opportunity for obtaining client feedback about any challenges they encountered and their satisfaction with the services received. While client self-report is an acceptable means to confirm linkage, clients sometimes tell us what we want to hear rather than what actually happened. For this reason, provider confirmation is the preferred means for confirming linkage.

Conclusion

HIV testing is a core component of the high-impact prevention approach. To make improvements along the HIV care continuum, to meet the goals of the NHAS, and to reduce the number of new HIV infections occurring each year in the United States, high-quality HIV testing services must be provided to the right populations in a timely way and with a focus on linkage to medical care, social, and behavioral services based on the client's test results and needs. HIV testing is important for identifying persons living with HIV early in their infection and for successfully linking them with medical care and treatment and prevention services. It is also important for identifying high-risk HIV-negative persons and successfully linking them with preventive services and treatment such as nPEP, PrEP, and social and behavioral services.

Chapter Summary

This Policy and Procedure has offered key information and operational guidance for HIV testing providers. We have outlined key principles and standards that all nonclinical HIV testing programs should meet, reviewed the importance of targeting and recruitment for HIV testing services, and provided an overview of HIV tests and testing technologies. We have provided step-by-step instructions for how to conduct an HIV testing session with your clients in nonclinical settings, discussed the importance of testing couples and sexual partners together, and reviewed the key elements of referral, linkage, and navigation services.

References

Cordes, L (2006). HIV & Sexual Assault: Considerations for Case Managers: Responding to disclosures of sexual assault. Case Manager Training. September 29, 2006.

Fisher, J.D., Fisher, W.A., Bryan, A.D. & Misovich, S.J. (2002). Information-Motivation-Behavioral Skills Model-Based HIV Risk Behavior Change Intervention for Inner-City High School Youth.

Fundamentals of HIV Prevention Counseling/Trainer's Manual, U.S. Department of Health and Human Services

HIV Counselor Training Manual, State of Connecticut Department of Public Health, AIDS & Chronic Diseases Section, June 30, 1995

HIV Testing Service for Counseling and testing Sites, Connecticut Department of Public health Laboratory-Specimen, Collection, Storage and Transport Guidelines. February, 2006.

HIV Counseling, Testing and Referral Standards and Guidelines, CDC, U.S. Department of Health and Human Services.

HIV Counseling, Testing, and Referral Services, Self-assessment tool for state and territorial health department. NASTAD.

Revised Guidelines for HIV Counseling, Testing and Referral, October 17, 2000, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Trisdale, S.K. (2005). Domestic Violence and HIV. Retrieved on July 29, 2008 from http://www.thewellproject.org/en_US/Womens_Center/Domestic_Violence_and_HIV.jsp

Implementing HIV Testing in Nonclinical Settings: A Guide for HIV Testing Providers. March 2, 2016, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Thank You

Lastly, CT DPH acknowledges the hard work and dedication of all frontline HIV testing providers, HIV prevention staff, and health care workers in the state of Connecticut. It is because of your care for the communities you live and work in, your compassion for your patients and clients, and your commitment to working smarter that advances continue to be made in HIV prevention in Connecticut. Thank you.

Glossary

AIDS: Acquired immunodeficiency syndrome. AIDS can affect the immune and central nervous systems and can result in neurological problems, infections, or cancers. It is caused by human immunodeficiency virus (HIV).

Anal sex: A type of sexual intercourse in which a man inserts his penis in his partner's anus. Anal sex can be insertive or receptive.

Anonymous: In anonymous testing, client identifying information is not linked to testing information, including the request for tests or test results.

Antiretroviral therapy: Treatment with drugs designed to prevent HIV from replicating in HIV-infected persons. Highly active antiretroviral therapy (HAART) is an antiretroviral regimen that includes multiple classifications of antiretroviral drugs.

Client-centered HIV prevention counseling: An interactive risk-reduction counseling model usually conducted with HIV testing, in which the counselor helps the client identify and acknowledge personal HIV risk behaviors and commit to a single, achievable behavior change step that could reduce the client's HIV risk.

CDC is the federal Centers for Disease Control and Prevention.

Client Recruitment: Strategies for identifying and engaging individuals living with HIV or at high risk of HIV infection in prevention interventions, including outreach encounters, receiving supported referrals from other agencies and MDPH disease intervention specialists, active in-reach within an agency, and public information activities. Recruitment should happen through street and off-site outreach (including Internet).

Confidentiality: Pertains to the disclosure of personal information in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the original disclosure. Confidentiality must be maintained for persons who are recommended and/or who receive HIV counseling, testing, and referral (CTR) services.

Confidential HIV test: An HIV test for which a record of the test and the test results are recorded in the client's chart.

Confirmatory test: A highly specific test designed to confirm the results of an earlier (screening) test. For HIV testing, a Western blot or, less commonly, an immunofluorescence assay (IFA) is used as a confirmatory test.

Cultural Competence: A set of attitudes, practices, or policies that respects rather than merely understands the differences between the cultures of individuals. This includes a thorough knowledge of a particular group's values, norms, mores, traditions, customs, arts, history, folklore, and institutions. The planning and provision of community activities, services and care should be conducted with capacity in culture, language, disabilities, developmental stage, socioeconomic status, sexual orientation, age, and gender identity. The selected interventions must be well suited to the language, culture, and behaviors of the given priority population.

Health service organizations and programs should be welcoming, physically accessible, and able to provide clients with appropriate resources and materials. Agencies should implement policies and practices, prohibit discrimination, and promote access and inclusion. The following knowledge, skills, and attitudes are critical to the successful implementation of culturally competent services:

- Understanding of the cultural factors affecting responsiveness to varying strategies;
- Understanding of clients' cultural norms, biases, and preferences;
- Knowledge of and understanding the impact that cultural norms can have on clients' decision making processes;
- Ability to adapt strategies to unique client characteristics and circumstances;
- Development of the willingness to be flexible in meeting clients' needs; and
- Development of a nonjudgmental and respectful acceptance of cultural, behavioral, and value differences.[1]

DIS: Disease Intervention Specialist is a professionally trained counselor who provides partner notification services for those who are HIV +. The goal of the DIS as it relates to Partner Notification is to work with HIV + clients on how to disclose their HIV status to partners at risk.

Early Linkage and Referral Initiative (ERLI) is a secondary prevention and early intervention service system developed by DPH to link HIV/AIDS-positive clients and high-risk HIV/AIDS-negative clients to Program and other support services.

eAuthentication is the process of establishing confidence in user identities electronically presented to an information system. It requires that users of CDC data systems have their identity 'authenticated', or verified, at the local level by authorized persons checking government issued IDs, such as driver licenses, U.S. passport or U.S. military ID cards.

EIA: Enzyme immunoassay. Sometimes referred to as ELISA (see next definition). A commonly used screening test to detect antibodies to HIV.

ELISA: Enzyme-linked immunosorbent assay. A type of EIA (see previous definition). A commonly used screening test to detect antibodies to HIV.

Engagement: The participation of a client and provider in an activity that involves positive interaction, whereby the client is made to feel as comfortable as possible while speaking to and listening to the provider. The first stage of engagement involves identifying and making contacts with priority population members and establishing rapport. The second stage of engagement involves supporting the client in considering the possibility of behavior change and providing information and skills building opportunities about risk behaviors and strategies to reduce or

[1] Adapted from the OFFICE OF HIV/AIDS Prevention & Education RFR and from "Outreach Competencies minimum standards for conducting street outreach for hard-to-reach populations." Developed by the Center for HIV, Hepatitis, and Addiction Training and Technology of the DC/Delaware Addiction Technology Transfer Center.

eliminate risk and reduce the harm that occurs as a result of these behaviors. The third stage of engagement involves supporting clients through the behavior change process and in maintaining the behaviors once they are established.[2]

Ethics: Standards, behavior or principles of conduct governing an individual or profession. As the field of HIV/AIDS prevention functions within a public health framework, the Public Health Code of Ethics[3] provides a general guide to ethical behavior for this field. Within the field of HIV/AIDS prevention staff are expected to treat all clients and colleagues with dignity and respect in order to foster an environment that is supportive of healthy behavior change that embraces harm reduction. As a general guide, any behavior that would cause potential current or future harm or distress to a client or colleague should be avoided. All OHA funded providers are required to develop a code of ethics to guide the delivery of their HIV/AIDS prevention & education activities.

As a minimum, the two following principles should be included in all ethical codes:

- Protect the confidentiality and privacy of all clients and client information, including written client records and information shared with the provider in the context of interventions or conversations. Program Managers/Coordinators should be familiar with local, state, and federal laws that govern confidentiality. Within CT, it is illegal to share information about an individual's HIV status with anyone or to test an individual for HIV without that individual's written consent.[4] Providers are expected to implement record keeping practices that protect client confidentiality. Client records should be maintained in a secure environment without any identifying information present that could link confidential information back to the client.
- Maintain appropriate boundaries with clients. For example, staff are expected to refrain from sexual or substance using behaviors with clients.

Evaluation: A process for determining how well health systems, either public or private, deliver or improve services and for demonstrating the results of resource investments.

EvaluationWeb: An online data collection and reporting system created by Luther Consulting, LLC.

False negative: A negative test result for a person who is actually infected.

False positive: A positive test result for a person who is actually not infected.

Freestanding HIV test site: A site that provides only HIV services. Sometimes referred to as alternate test site or anonymous test site.

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[2] "Outreach Competencies: Minimum Standards for Conducting Street Outreach for Hard to Reach Populations." Center for HIV, Hepatitis, and Addiction Training and Technology of the DC/Delaware Addiction Technology Transfer Center. (Page 16).

[3] http://www.apha.org/codeofethics/ The American Psychological Code of Ethics may be found at: http://www.apa.org/ethics/ and the National Association of Social Workers Code of Ethics may be found at: http://www.socialworkers.org/pubs/code/code.asp Both may also serve as useful examples of elements to be included in your agency code of ethics.

[4] Massachusetts General Laws, Ch. 111, sec. 70F

Harm Reduction refers to a range of public health policies designed to reduce the harmful consequences associated with human behaviors, even if those behaviors are risky or illegal

HIV: Human immunodeficiency virus, which causes AIDS. Several types of HIV exist, with HIV-1 being the most common in the United States.

HIV test: More correctly referred to as an HIV antibody test, the HIV test is a laboratory procedure that detects antibodies to HIV, rather than the virus itself.

HIV prevention counseling: An interactive process between client and counselor aimed at reducing risky sex and needle-sharing behaviors related to HIV acquisition (for HIV-uninfected clients) or transmission (for HIV-infected clients). See also client centered HIV prevention counseling.

Home sample collection test: A test that a consumer purchases and uses to collect blood (or other bodily fluid) and then send it out for testing. Counseling and test results are typically provided by telephone using user-generated codes to ensure confidentiality and anonymity.

Implementation Plan: A required annual intervention plan that describes how each intervention supported by the DPH HIV Prevention Unit will be implemented.

Incidence: In epidemiology, the number of new cases of infection or disease that occur in a defined population within a specified time.

Indeterminate test result: A possible result of a Western blot, which might represent a recent HIV infection or a false-positive.

Information: In the context of HIV counseling, information encompasses the topics HIV transmission and prevention and the meaning of HIV test results.

Informed consent: The legally effective permission of a client or legally authorized representative (e.g., parent or legal guardian of a minor child) to undergo a medical test or procedure.

Medication Adherence Program Services is a comprehensive service to assist People Living with HIV/AIDS who are starting or on HIV medications to adhere to their treatment regimen. Staff offer ongoing support to help clients to develop and implement strategies to overcome barriers in adhering to their medications.

Motivational Interviewing (MI): A clinical approach that helps people with mental health and substance use disorders and other chronic conditions such as diabetes, cardiovascular conditions, and asthma make positive behavioral changes to support better health.

Negative predictive value: A negative predictive value estimates the probability that a person with a negative diagnostic test result will actually not be infected.

Nonoccupational HIV exposure: A reported sexual, injection-drug–use, or other nonoccupational HIV exposure that might put a patient at high risk for acquiring HIV infection.

Nucleic acid amplification testing: A type of testing that identifies viral genes (e.g., specific sequences of nucleic acids) using gene amplification technologies such as polymerase chain reaction (PCR).

Occupational HIV exposure: An occupational exposure to HIV that occurs during the performance of job duties. Defined as a percutaneous injury (e.g., a needlestick or cut with a sharp object), contact of mucous membranes, or contact of skin (especially when the exposed skin is chapped, abraded, or afflicted with dermatitis or the contact is prolonged or involving an extensive area) with blood, tissues, or other body fluids to which universal precautions apply.

Oral fluid test: A test using oral mucosal transudate, a serous fluid. To differentiate this fluid from saliva, an absorbent material is left in the mouth for several minutes. In an HIV-infected person, oral mucosal transudate is likely to contain HIV antibodies.

Oral sex: A type of sexual intercourse in which the partner's genitals are stimulated by mouth and tongue.

Outreach is defined as approaching program eligible persons and recruiting them for enrollment into a program.

Partner Services (PS): A prevention activity that aims to a) provide services to HIV-infected persons and their sex and needle-sharing partners so they can reduce their risk for infection or, if already infected, can prevent transmission to others and b) help partners gain earlier access to individualized counseling, HIV testing, medical evaluation, treatment, and other prevention and support services.

Perinatal HIV transmission: Transmission of HIV from the mother to the fetus or infant during pregnancy, delivery, or breast-feeding.

Program Evaluation Monitoring System (PEMS): PEMS is a national data reporting system that includes a standardized set of HIV prevention data variables, web-based software for data entry and management.

Prevention Counseling an interactive client-focused, using education, skills-building, role plays, support, crisis management, and other strategies to help clients reduce and eliminate risk behaviors and maintains thee changes over the long term.

Positive predictive value: A positive predictive value estimates the probability that a person with a positive diagnostic test result will actually be infected.

Positive test: For HIV, a specimen sample that is reactive on an initial ELISA test or a confirmed positive on Western blot or other supplemental test indicates that the client is infected.

Prevalence: The number or percentage of persons in a given population with a disease or condition at a given point in time.

Prevention counseling: An interactive process between client and counselor aimed at reducing risky sex and needle-sharing behaviors related to HIV acquisition (for HIV uninfected clients) or

transmission (for HIV-infected clients). See also client-centered HIV prevention counseling and HIV prevention counseling.

Quality assurance: An ongoing process for ensuring that the prevention program effectively delivers a consistently high level of service to the clients.

Rapid HIV test: A test to detect antibodies to HIV that can be collected and processed within a short interval of time (e.g., approximately 10–60 minutes).

Referral: The process through which a client is connected with services to address prevention needs (medical, prevention, and psychosocial support).

Risk assessment: Risk assessment is a fundamental part of a client-centered HIV prevention counseling session in which the client is encouraged to identify, acknowledge, and discuss in detail his or her personal risk for acquiring or transmitting HIV.

Risk screening: A brief evaluation of HIV risk factors, both behavioral and clinical, used for decisions about who should be recommended HIV counseling and testing. Risk screening is different from risk assessment.

Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87, October 30, 2009). The legislation was first enacted in 1990 as the Ryan White CARE (Comprehensive AIDS Resources Emergency) Act. It has been amended and reauthorized four times: in 1996, 2000, 2006, and 2009.

Screening test: An initial test, usually designed to be sensitive, to identify all persons with a given condition or infection (e.g., enzyme immunoassay [EIA] or enzyme-linked immunosorbent assay [ELISA]).

Sensitivity: The probability that a test will be positive when infection or condition is present.

Seroconversion: Initial development of detectable antibodies specific to a particular antigen; the change of a serologic test result from negative to positive as a result of antibodies induced by the introduction of antigens or microorganisms into the host.

Specificity: The probability that a test will be negative when the infection or condition is not present.

Tuberculosis (TB) disease: Active disease caused by Mycobacterium tuberculosis, as evidenced by a confirmatory culture, or, in the absence of culture, suggestive clinical symptoms, including productive cough lasting >3 weeks, chest pain, hemoptysis, fever, night sweats, weight loss, and easy fatigability. Active TB is a communicable disease that is treatable, curable, and preventable, and persons with active TB disease should be under the care of a health-care provider. Active TB disease could indicate immune deficiency. For HIV-infected persons, active TB disease is considered an opportunistic infection and a qualifying condition for AIDS.

Tuberculosis (TB) infection: Infection with the bacteria M. tuberculosis, as evidenced by a positive tuberculin skin test (TST) that screens for infection with this organism. Sometimes, TST is called a purified protein derivative (PPD) or Mantoux test. A positive skin test might or might

not indicate active TB disease (see tuberculosis disease). Thus, any person with a positive TST should be screened for active TB and, once active TB is excluded, evaluated for treatment to prevent the development of TB disease. TB infection alone is not considered an opportunistic infection indicating possible immune deficiency.

Vaginal sex: A type of sexual intercourse in which the man's penis enters the woman's vagina.

Venue: A descriptor of the context or setting within which HIV prevention interventions are delivered with specific reference to the physical or institutional environment where a given intervention is located (e.g. clinic, drop-in-center, bar, etc.). The prevention intervention can take place in a variety of venues, including but not limited to, the Internet, public sex environments, drug purchasing and using environments, sex work environments, drop-in centers, clinical settings, religious institutions and settings, community centers and social centers, educational settings, prisons, jails and other correctional facilities, and homeless shelters. The venue should be a place where the priority population is comfortable and where the education can be successfully executed. In all cases, the program must describe why a chosen venue is well suited to the needs of their stated priority population and should indicate the specific nature of the chosen venue.

Voluntary HIV testing: HIV testing that is offered free of coercion. With voluntary HIV testing, participants have the opportunity to accept or refuse HIV testing.

Western blot: A laboratory test that detects specific antibodies to components of a virus. Chiefly used to confirm HIV antibodies in specimens found repeatedly reactive using ELISA.

Work Plan: Required annual plan that describes the performance goals and objectives of each intervention supported by the DPH HIV Prevention Unit.

Appendixes

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

☐ Initial Application ☐ Survey ☐ Change in Certificate Type ☐ Other Changes (Specify) _____ Effective Date _____	CLIA IDENTIFICATION NUMBER _____ D _____ *(If an initial application leave blank, a number will be assigned)*
FACILITY NAME	FEDERAL TAX IDENTIFICATION NUMBER
EMAIL ADDRESS	TELEPHONE NO. *(Include area code)* / FAX NO. *(Include area code)*
FACILITY ADDRESS — ***Physical Location of Laboratory (Building, Floor, Suite if applicable.)*** *Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified* NUMBER, STREET *(No P.O. Boxes)*	MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate* NUMBER, STREET
CITY / STATE / ZIP CODE	CITY / STATE / ZIP CODE
SEND FEE COUPON TO THIS ADDRESS ☐ Physical ☐ Mailing ☐ Corporate SEND CERTIFICATE TO THIS ADDRESS ☐ Physical ☐ Mailing ☐ Corporate	CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate* NUMBER, STREET
NAME OF DIRECTOR *(Last, First, Middle Initial)*	CITY / STATE / ZIP CODE
CREDENTIALS	**FOR OFFICE USE ONLY** Date Received _____

II. TYPE OF CERTIFICATE REQUESTED *(Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)*

☐ Certificate of Waiver *(Complete Sections I – VI and IX – X)*

☐ Certificate for Provider Performed Microscopy Procedures (PPM) *((Complete Sections I-VII and IX-X)*

☐ Certificate of Compliance *(Complete Sections I – X)*

☐ Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.

☐ The Joint Commission ☐ AOA ☐ AABB ☐ A2LA

☐ CAP ☐ COLA ☐ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. Expiration Date: 3/31/2021. The time required to complete this information collection is estimated to average one hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. *****CMS Disclaimer*****Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact LabExcellence@cms.hhs.gov.

III. TYPE OF LABORATORY *(Check the one most descriptive of facility type)*

- ☐ 01 Ambulance
- ☐ 02 Ambulatory Surgery Center
- ☐ 03 Ancillary Testing Site in Health Care Facility
- ☐ 04 Assisted Living Facility
- ☐ 05 Blood Bank
- ☐ 06 Community Clinic
- ☐ 07 Comp. Outpatient Rehab Facility
- ☐ 08 End Stage Renal Disease Dialysis Facility
- ☐ 09 Federally Qualified Health Center
- ☐ 10 Health Fair
- ☐ 11 Health Main. Organization
- ☐ 12 Home Health Agency
- ☐ 13 Hospice
- ☐ 14 Hospital
- ☐ 15 Independent
- ☐ 16 Industrial
- ☐ 17 Insurance
- ☐ 18 Intermediate Care Facilities for Individuals with Intellectual Disabilities
- ☐ 19 Mobile Laboratory
- ☐ 20 Pharmacy
- ☐ 21 Physician Office
- ☐ 22 Practitioner Other *(Specify)* _____
- ☐ 23 Prison
- ☐ 24 Public Health Laboratories
- ☐ 25 Rural Health Clinic
- ☐ 26 School/Student Health Service
- ☐ 27 Skilled Nursing Facility/ Nursing Facility
- ☐ 28 Tissue Bank/Repositories
- ☐ 29 Other *(Specify)* _____

IV. HOURS OF LABORATORY TESTING *(List times during which **laboratory testing** is performed in HH:MM format)* *If testing 24/7 Check Here* ☐

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES *(must meet one of the regulatory exceptions to apply for this provision in 1-3 below)*

Are you applying for a single site CLIA certificate to cover multiple testing locations?

☐ No. If no, go to section VI. ☐ Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address?

   ☐ Yes ☐ No

   If yes and a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?

   ☐ Yes ☐ No

   If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?

   ☐ Yes ☐ No

   If yes, provide the number of sites under this certificate _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ☐ and attach the additional information using the same format.

NAME AND ADDRESS/LOCATION		TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION *(Number, Street, Location if applicable)*		
CITY, STATE, ZIP CODE	TELEPHONE NO. *(Include area code)*	
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION *(Number, Street, Location if applicable)*		
CITY, STATE, ZIP CODE	TELEPHONE NO. *(Include area code)*	

In the next three sections, indicate testing performed and annual test volume.

VI. WAIVED TESTING *If only applying for a Certificate of Waiver, complete this section and skip sections VII (PPM Testing) and VIII (Non-Waived Testing).*

Identify the waived testing (to be) performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.

e.g. (Rapid Strep, Acme Home Glucose Meter)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed _____

☐ Check if no waived tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

VII. PPM TESTING *If only applying for a Certificate for PPM, complete this section and skip section VIII (Non-Waived Testing).*

Identify the PPM testing (to be) performed. Be as specific as possible.

e.g. (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed _____

If also performing waived complexity tests, complete Section VI. For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the specialty/subspecialty category and the "total estimated annual test volume" in section VIII.

☐ Check if no PPM tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

VIII. NON-WAIVED TESTING *(Including PPM testing if applying for a Certificate of Compliance or Accreditation) Complete this section only if you are applying for a Certificate of Compliance or a Certificate of Accreditation.*

Identify the non-waived testing (to be) performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory e.g. (Potassium, Acme Chemistry Analyzer).

If additional space is needed, check here ☐ and attach additional information using the same format.

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the instructions included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/ subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AOA, AABB, A2LA ,CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY 010			**HEMATOLOGY 400**		
☐ Transplant			☐ Hematology		
☐ Nontransplant			**IMMUNOHEMATOLOGY**		
MICROBIOLOGY			☐ ABO Group & Rh Group 510		
☐ Bacteriology 110			☐ Antibody Detection (transfusion) 520		
☐ Mycobacteriology 115			☐ Antibody Detection (nontransfusion) 530		
☐ Mycology 120			☐ Antibody Identification 540		
☐ Parasitology 130			☐ Compatibility Testing 550		
☐ Virology 140			**PATHOLOGY**		
DIAGNOSTIC IMMUNOLOGY			☐ Histopathology 610		
☐ Syphilis Serology 210			☐ Oral Pathology 620		
☐ General Immunology 220			☐ Cytology 630		
CHEMISTRY			**RADIOBIOASSAY 800**		
☐ Routine 310			☐ Radiobioassay		
☐ Urinalysis 320			**CLINICAL CYTOGENETICS 900**		
☐ Endocrinology 330			☐ Clinical Cytogenetics		
☐ Toxicology 340			**TOTAL ESTIMATED ANNUAL TEST VOLUME:**		

IX. TYPE OF CONTROL (check the one most descriptive of ownership type)

VOLUNTARY NONPROFIT	FOR PROFIT	GOVERNMENT
☐ 01 Religious Affiliation	☐ 04 Proprietary	☐ 05 City
☐ 02 Private Nonprofit		☐ 06 County
☐ 03 Other Nonprofit		☐ 07 State
_____ *(Specify)*		☐ 08 Federal
		☐ 09 Other Government
		_____ *(Specify)*

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

PRINT NAME OF OWNER/DIRECTOR OF LABORATORY

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY ***(Sign in ink)***	DATE

NOTE: Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application.

STATE AGENCY CONTACT INFORMATION CAN BE FOUND AT:
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION (FORM CMS-116)

INSTRUCTIONS FOR COMPLETION

CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service are not considered laboratories. CLIA does not apply to a facility that only performs forensic testing. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

The CLIA application (Form CMS-116) collects information about your laboratory's operation which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. All information submitted should be based on your facility's laboratory operation as of the date of form completion.

NOTE: WAIVED TESTS ARE NOT EXEMPT FROM CLIA. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST APPLY FOR A CLIA CERTIFICATE OF WAIVER.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M (42 CFR PART 493) of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application. Information to be submitted with the application include:

- **Verification of State Licensure, as applicable**
- **Documentation of qualifications:**
  - **Education (copy of Diploma, transcript from accredited institution, CMEs),**
  - **Credentials, and**
  - **Laboratory experience.**

Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of their education to education obtained in the United States. Failure to submit this information will delay the processing of your application.

ALL APPLICABLE SECTIONS MUST BE COMPLETED. INCOMPLETE APPLICATIONS CANNOT BE PROCESSED AND WILL BE RETURNED TO THE FACILITY. PRINT LEGIBLY OR TYPE INFORMATION.

I. GENERAL INFORMATION

For an initial applicant, check **"initial application"**. For an initial survey or for a recertification, check **"survey"**. For a request to change the type of certificate, check **"change in certificate type"** and provide the effective date of the change. For all other changes, including change in location, director, lab closure, etc., check **"other changes"** and provide the effective date of the change.

CLIA Identification Number: For an initial applicant, the CLIA number should be left blank. The number will be assigned when the application is processed. For all other applicants, enter the 10 digit CLIA identification number already assigned and listed on your CLIA certificate.

Facility Name: Be specific when indicating the name of your facility, particularly when it is a component of a larger entity, e.g., respiratory therapy department in XYZ Hospital. For a physician's office, this may be the name of the physician. NOTE: the information provided is what will appear on your certificate.

Physical Facility Address: This address is mandatory and must reflect the physical location where the laboratory testing is performed. The address may include a floor, suite and/or room location, but cannot be a Post Office box or Mail Stop.

If the laboratory has a separate mailing and/or corporate address (from the Facility Address), please complete the appropriate sections on the form.

Mailing Address: This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to an alternate location, such as an accounts payable office. A Post Office box number or Mail Stop number may be used as part of the Mailing Address for this section.

Corporate Address: This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to another location, such as, the main headquarters or home office for the laboratory. A Post Office box number or Mail Stop number may be used as part of the Corporate Address for this section.

Form Mailing: Select the address (Physical, Mailing, Corporate) where the CLIA fee coupon and CLIA certificate are to be mailed.

For Office Use Only: The date received is the date the form is received by the state agency or CMS regional office for processing.

II. TYPE OF CERTIFICATE REQUESTED

Select your certificate type based on the highest level of test complexity performed by your laboratory. A laboratory performing non-waived tests can choose Certificate of Compliance or Certificate of Accreditation based on the agency you wish to survey your laboratory.

When completing this section, please remember that a facility holding a: **Certificate of Waiver** can only perform tests categorized as waived;*

- **Certificate for Provider Performed Microscopy Procedures** (PPM) can only perform tests categorized as PPM, or tests categorized as PPM and waived tests;*

- **Certificate of Compliance** can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the applicable CLIA quality standards are met following a CLIA survey; and
- **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/or high complexity non-waived tests provided the laboratory is currently accredited by an approved accreditation organization. (If your CMS-approved accreditation organization is not listed, contact your local State Agency for further instructions.)

*A current list of waived and PPM tests may be obtained from your State agency. Specific test system categorizations can also be found on the Internet at: **http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm**.

III. TYPE OF LABORATORY

Select the type that is most descriptive of the location where the laboratory testing is performed.

If selecting 'mobile laboratory' (code 19), a mobile laboratory is defined as a movable, self-contained operational laboratory with its own personnel, equipment, and records. For record keeping purposes, include, on a separate sheet of paper, the vehicle identification numbers (VINs) of all vehicles used for mobile laboratory testing.

If selecting 'Practitioner Other' (code 22), this type includes practitioners such as, dentists, chiropractors, etc.

IV. HOURS OF ROUTINE OPERATION

Provide only the times when actual laboratory testing is performed in your facility. Please use the HH:MM format and check box marked '24/7' if laboratory testing is performed continuously, e.g., 24 hours a day, 7 days a week. Do not use military time.

V. MULTIPLE SITES

You can only qualify for the multiple site provision (more than one site under one certificate) if you meet one of the CLIA requirements described in 42 CFR 493. 493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3) Hospice and HHA could qualify for an exception.

VI. WAIVED TESTING

Indicate the estimated total annual test volume for all waived tests performed. List can be found at: **http:www.cms.gov/CLIA/downloads/waivetbl.pdf**

VII. PPM TESTING

Indicate the estimated total annual test volume for all PPM tests performed. List can be found at: **https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ppmplist.pdf**

VIII. NON-WAIVED TESTING *(INCLUDING PPM)*

The total Estimated Annual Test volume in this section includes all non-waived testing, including PPM tests previously counted in section VII. Follow the specific instructions on page 3 of the Form CMS-116 when completing this section for test counting information. (Note: The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., CAP, etc.).

IX. TYPE OF CONTROL

Select the type of ownership or control which most appropriately describes your facility.

X. DIRECTOR OF ADDITIONAL LABORATORIES

List all other facilities for which the director is responsible and that are under different certificates. Note that for a Certificate of PPM, Certificate of Compliance or Certificate of Accreditation, an individual can only serve as the director for no more than five certificates.

Reminders - Before submitting the Form CMS-116:

1. Include the current or estimated annual test volume.
2. For Certificate for PPM, Certificate of Compliance, or Certificate of Accreditation, include the laboratory director qualifications.
3. Do not send any money with your application.
4. Send the completed Form CMS-116 to the appropriate State Agency **(http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf)**.

Once the completed Form CMS-116 has been returned to the applicable State agency and it is processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee. If you are applying for a Certificate of Compliance or Certificate of Accreditation, you will initially pay for and receive a Registration Certificate. A Registration Certificate permits a facility requesting a Certificate of Compliance to perform testing until an onsite inspection is conducted to determine program compliance; or for a facility applying for a Certificate of Accreditation, until verification of accreditation by an approved accreditation organization is received by CMS.

If you need additional information concerning CLIA, or if you have questions about completion of this form, please contact your State agency. State agency contact information can be found at: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

TESTS COMMONLY PERFORMED AND THEIR CORRESPONDING LABORATORY SPECIALTIES/SUBSPECIALITIES

HISTOCOMPATIBILITY (010)
HLA Typing (disease associated antigens)

MICROBIOLOGY

Bacteriology (110)
Gram Stain
Culture
Susceptibility
Strep screen
Antigen assays (H.pylori, Chlamydia, etc.)

Mycobacteriology (115)
Acid Fast Smear
Mycobacterial culture
Mycobacterial susceptibility

Mycology (120)
Fungal Culture
DTM
KOH Preps

Parasitology (130)
Direct Preps
Ova and Parasite Preps
Wet Preps

Virology (140)
RSV (Not including waived kits)
HPV assay
Cell culture

DIAGNOSTIC IMMUNOLOGY

Syphilis Serology (210)
RPR
FTA, MHATP

General Immunology (220)
Allergen testing
ANA
Antistreptolysin O
Antigen/Antibody (hepatitis, herpes, rubella, etc.)
Complement (C3, C4)
Immunoglobulin
HIV
Mononucleosis assay
Rheumatoid factor
Tumor marker (AFP, CA 19-9, CA 15-3, CA 125)*

*Tumor markers can alternatively be listed under Routine Chemistry instead of General Immunology.

HEMATOLOGY (400)
Complete Blood Count (CBC)
WBC count
RBC count
Hemoglobin
Hematocrit (Not including spun micro)
Platelet count
Differential
Activated Clotting Time
Prothrombin time (Not including waived instruments)
Partial thromboplastin time
Fibrinogen
Reticulocyte count
Manual WBC by hemocytometer
Manual platelet by hemocytometer
Manual RBC by hemocytometer
Sperm count

IMMUNOHEMATOLOGY
ABO group (510)
Rh(D) type (510)
Antibody screening
Antibody identification (540)
Compatibility testing (550)

PATHOLOGY
Dermatopathology
Oral Pathology (620)
PAP smear interpretations (630)
Other Cytology tests (630)
Histopathology (610)

RADIOBIOASSAY (800)
Red cell volume
Schilling test

CLINICAL CYTOGENETICS (900)
Fragile X
Buccal smear
Prader-Willi syndrome
FISH studies for: neoplastic disorders, congenital disorders or solid tumors.

CHEMISTRY

Routine Chemistry (310)
Albumin
Ammonia
Alk Phos
ALT/SGPT
AST/SGOT
Amylase
Bilirubin
Blood gas (pH, pO2, pCO2)
BUN
Calcium
Chloride
Cholesterol
Cholesterol, HDL
CK/CK isoenzymes
CO2
Creatinine
Ferritin
Folate
GGT
Glucose (Not fingerstick)
Iron
LDH/LDH isoenzymes
Magnesium
Potassium
Protein, electrophoresis
Protein, total
PSA
Sodium
Triglycerides
Troponin
Uric acid
Vitamin B12

Endocrinology (330)
Cortisol
HCG (serum pregnancy test)
T3
T3 Uptake
T4
T4, free
TSH

Toxicology (340)
Acetaminophen
Blood alcohol
Blood lead (Not waived)
Carbamazepine
Digoxin
Ethosuximide
Gentamicin
Lithium
Phenobarbital
Phenytoin
Primidone
Procainamide
NAPA
Quinidine
Salicylates
Theophylline
Tobramycin
Therapeutic Drug Monitoring

Urinalysis (320)**
Automated Urinalysis (Not including waived instruments)
Microscopic Urinalysis
Urine specific gravity by refractometer
Urine specific gravity by urinometer
Urine protein by sulfosalicylic acid

** Dipstick urinalysis is counted in Section VI. WAIVED TESTING

NOTE: This is not a complete list of tests covered by CLIA. Other non-waived tests and their specialties/ subspecialties can be found at **http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/SubjecttoCLIA.pdf** and **http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/lccodes.pdf.** You may also call your State agency for further information. State agency contact information can be found at: **http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf**.

GUIDELINES FOR COUNTING TESTS FOR CLIA

- For **histocompatibility**, each HLA typing (including disease associated antigens), HLA antibody screen, or HLA crossmatch is counted as one test.
- For **microbiology**, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per specimen regardless of the extent of identification, number of organisms isolated and number of tests/procedures required for identification.
- For **general immunology**, testing for allergens should be counted as one test per individual allergen.
- For **hematology**, each **measured** individual analyte of a **complete blood count** or **flow cytometry** test that is ordered **and reported** is counted separately. The **WBC differential** is counted as one test.
- For **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test.
- For **histopathology**, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.
- For **cytology**, each slide (not case) is counted as one test for both Pap smears and nongynecologic cytology.
- For **clinical cytogenetics**, the number of tests is determined by the number of specimen types processed on each patient; e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests.
- For **chemistry**, each analyte in a profile counts as one test.
- For **urinalysis**, microscopic and macroscopic examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.
- For **all specialties/subspecialities**, do not count calculations (e.g., A/G ratior, MCH, T7, etc.), quality control, quality assurance, or proficiency testing assays.

If you need additional information concerning counting tests for CLIA, please contact your State agency.

Submitter Facility Name/Address	CLINICAL TEST REQUISITION STATE OF CONNECTICUT Dr. Katherine A. Kelley State Public Health Laboratory 395 West Street, Rocky Hill, CT 06067 CLIA ID 07D0644555 / CT License CL-0197 Phone 860-920-6500 **CLIENT SERVICES 860-920-6635**	***ACCESSION LABEL FOR CTDPH LABORATORY USE ONLY***
♦**LAB PROFILE Number:**		

♦ **DENOTES REQUIRED INFORMATION**

Section 1: Patient Information (*Please Print Clearly*)

♦ **Name (Last, First, M.I.) or Identifier:**

♦ **Street Address:** | ♦ **City, State, Zip:**

♦ **Date of Birth:** | Gender: ☐ Female ☐ Male ☐ Unknown | Home Phone:

Race (check all that apply): **(♦ Race/Ethnicity Information is Required for Blood Lead)**

☐ White ☐ Black/African Amer. ☐ Asian ☐ Amer. Indian/Alaska Nat. ☐ Nat. Hawaiian/Other Pacific Islander ☐ Other ☐ Unknown

Ethnicity: ☐ Hispanic ☐ Non-Hispanic ☐ Unknown

Ordering Healthcare Provider: | Phone:

Section 2: Specimen Information

♦ **Specimen Storage (Prior to Delivery):** ☐ Refrigerated (2-8˚C) ☐ Frozen (<-20˚C) ☐ Ambient Temperature

♦ **Specimen Transport/Delivery:** ☐ Cold (Ice pack) ☐ Frozen (Dry Ice) ☐ Ambient Temperature

Submitter Sample ID: | ♦ **Date Collected:** | Time Collected: ☐ AM ☐ PM

♦ **Specimen Source/Type:**

☐ Blood (whole) ☐ Bronchial Wash ☐ Buccal cavity ☐ Cervix ☐ CSF ☐ Nasopharynx ☐ Oropharynx ☐ Plasma
☐ Rectal ☐ Serum ☐ Sputum ☐ Stool ☐ Urethra ☐ Urine ☐ Vaginal

☐ Body Fluid, specify _____ ☐ Tissue, specify _____

☐ Other, specify

♦ Section 3: Select Testing Requested

Bacteriology

☐ AFB Clinical Specimen (Mycobacteria Smear & Culture)
☐ AFB Referred Culture (Mycobacteria for Identification)
☐ Bioterrorism Agent Identification
specify agent:_____
☐ Bordetella pertussis (DFA, Culture) ☐ (DNA amplification)
☐ Chlamydia/ Gonorrhea Nucleic Acid Amplification Test
☐ CRE panel Organism:_____
☐ EIP Isolates for Identification **(Check one)**
☐ Group A *Streptococcus* ☐ *H. influenzae* ☐ *L. monocytogenes*
☐ *N. meningitidis* ☐ *S. pneumoniae* ☐ Other: _____
☐ Enteric Isolate for Identification
☐ *Campylobacter* ☐ *E. coli O157* ☐ *Salmonella* ☐ *Shigella*
☐ *Shiga-toxin producing E. coli* ☐ *Vibrio* ☐ Other: _____
☐ Enteric (Stool) Culture ☐ CIDT Organism: _____
☐ Shiga-toxin (+) Broth Culture

Bacterial Serology

☐ QuantiFeron-TB Test **(Specify ♦ Date & Time Collected Above)**
☐ Syphilis Screen (VDRL)
☐ Syphilis Confirmation (VDRL & TP-PA)
☐ Syphilis CSF (VDRL Only)

Blood Lead **(Uninsured Patients ONLY)** ♦ **Race/Ethnicity Required**

☐ Child Lead Screen (Capillary Blood)
☐ Lead Confirmation (Venous Blood)

Mycology

☐ *Candida auris* identification

Parasitology

☐ Blood Parasite - Smear

Virology

☐ Arbovirus IgG/IgM (Encephalitis Viruses)
California Group, Eastern Equine, St. Louis, Western Equine
☐ Cytomegalovirus IgG Antibody
☐ Cytomegalovirus IgM Antibody
☐ Hepatitis B Surface Antibody
☐ Hepatitis B Surface Antigen
☐ Hepatitis C Testing
☐ Herpes Simplex IgG Antibody
☐ Herpes Simplex DNA amplification
☐ HIV-1/HIV-2 Ag/Ab
☐ HIV Viral Load
☐ Influenza PCR
☐ Measles PCR
☐ MERS CoV (Novel Coronavirus) **(Epidemiology Approval Required)**
☐ Mumps PCR
☐ Norovirus PCR **(Epidemiology Approval Required)**
☐ Respiratory Virus Antigen Panel: *Adenovirus, Human Metapneumovirus, Parainfluenza, Rhinovirus/Enterovirus, RSV*
☐ Varicella Zoster IgG Antibody
☐ West Nile Virus IgM Antibody
☐ Virus Identification (Tissue Culture)
NOTE: Zika virus testing requires submission of the Zika Virus Clinical Test Requisition

Test, Agent or Disease, Not Listed (Specify)

Comments

CT DPH laboratory Procedure & Submission of Samples

This appendix provides an overview of Department of Public Health (DPH procedure for the submitting HIV related samples/specimens. HIV and AIDS surveillance methods in Connecticut, defines surveillance, prevalence and incidence and instructs new counselor how to report their HIV positive cases to the Department of Public Health.

CT DPH Specimen Collection, Storage and Transportation Procedures

HIV Testing Services for Testing Sites

The Connecticut Department of Public Health (CTDPH) Laboratory, Serology Unit, performs HIV-1/2 antibody and antigen testing using ARCHITECT HIV Ag/Ab Combo and supplemental testing with Multispot HIV-1/HIV-2 Rapid Test. Staff is available for consultation and questions Monday through Friday, 8:00 AM to 4:00 PM (Serology Laboratory: Ph: (860) 920-6674; Fax: (860) 920-6710. Organizations wishing to provide HIV Testing with CT DPH resources must contact the DPH TB, HIV, STD, & Viral Hepatitis Program to set up testing services and acquire appropriate documentation and forms.

Collection of Specimen

The US Food and Drug Administration (FDA) have approved a variety of testing technologies for diagnostic use. These tests allow for the testing of HIV antibodies using whole blood, serum, and oral fluids. Publicly funded HIV testing sites in Connecticut are able to utilize Alere Determine™ HIV-1/2 Ag/Ab Combo for specimen collection.
Phlebotomy

Phlebotomy or Venipuncture is the puncture of a vein in order to obtain blood. The blood is usually taken from the arm with a needle and a tube for collection. Phlebotomy training can be provided at local hospitals or community colleges. Universal precautions for infection control, in compliance with the OSHA standard must be followed.

Waived Rapid Test

The development of rapid testing technology to detect HIV infection has created new opportunities for funded providers and community-based organizations currently offering HIV testing. The OPH currently uses Alere Determine™ HIV-1/2 Ag/Ab Combo for specimen collection, which is manufactured by Alere. The waived rapid test is a single-use, qualitative, immunoassay to detect antibodies and P-24 antigen to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV2) in fingerstick whole blood, and venipuncture whole blood and plasma specimens.

A Non-Reactive test result means that HIV 1 and HIV 2 antibodies were not detected in the specimen therefore the test result is negative (-) for HIV. A Reactive test result means that HIV-1 or HIV-2 antibodies or p-24 antigen have been detected in the specimen. The test result is interpreted as PRELIMINARY POSITIVE for HIV-1 and /or HIV-2*. All reactive (preliminary positive) rapid test results must be confirmed with a supplemental test. A new specimen must be obtained by venipuncture. Specimens sent to the CT DPH laboratory for confirmation should be identified as testing reactive by antibody or P-24 antigen with a rapid HIV antibody test. The CT DPH laboratory will confirm the reactive result. If the specimen is reactive with the ARCHITECT HIV Ag/Ab Combo, the lab will perform a Multispot HIV-1/HIV-2 Rapid Test that will confirm only a positive antibody result; If the specimen is positive with the ARCHITECT HIV Ag/Ab Combo but negative with the Multispot HIV-1/HIV-2 Rapid Test, the specimen will need to be confirmed by sending out the sample for a NAT-1 (Nucleic Acid Testing).

Alere Determine™ HIV-1/2 Ag/Ab Combo

The development of rapid testing technology to detect HIV infection has created new opportunities for funded providers and community-based organizations currently offering HIV screening to increase testing options available to clients. The DPH currently offers Alere Determine™ HIV-1/2 Ag/Ab Combo.

Submission of Samples

Submission of samples and paperwork to the State of CT DPH Laboratory and to the HIV Prevention Program as follows:

Sites that send blood samples to the State Laboratory for the HIV testing:

- Fill out HIV Test Form (HIV Test 1 column) when the client decides to test for HIV.
- Send the blood device for testing to the lab. HIV Test kits sent to sites include:
    - 1- 7ml yellow speckle test tube,
    - 1 plastic tube with closure top,
    - 1 small sheet of absorbent material,
    - 1 aluminum tube with screw top cap,
    - 1 requisition sheet,
    - 1 cylindrical cardboard mailer with screw cap top.
- Put the tube of blood (with the HIV Test Form ID number attached to the specimen) into the plastic bag, and put both into the appropriate container (metal container or envelope). The HIV Test Form ID Number should be wrapped around the metal cylinder or folder around specimens.
- Put the metal container into the cardboard outer container.
- Put specimens and paperwork (Required forms) into the padded envelope and mail it to the State Virology Laboratory, 395 West Street, Rocky Hill, CT 06067 via first class U.S. mail.
- HIV Test Form ID number must be included in the lab requisition form.
- Up to 10 specimens can be mailed in a single envelope.
- HIV Test Forms 1, 2, and 3 for all confirmed positives must be mailed to: Data Management, HIV Prevention Program, MS#llAPV, 410 Capitol Avenue, Hartford, CT, 06134 within seven days of confirmation.
- All HIV Test Forms must have corresponding HIV Test Form ID Label.
- Keep copies of the HIV Test Forms in your files for you records.

Before the specimen is mailed, be sure:

- That each specimen to be tested has an accompanying HIV Test Form ID Number to connect the specimen to the client.
- That someone has checked the identification numbers on the specimen tube and the paperwork to be sure that they match

Sites that screen with HIV Rapid Test Kits:

- Sites that have preliminary positives must draw a blood sample for confirmation and follow the submission protocol detailed above.
- Mail in the Parts 1, 2, and 3 if results are confirmed as a positive case and keep all HIV Test Forms part 1 with negative results on file (Note. Do not submit HIV Test Form Part 1 negatives to DPH}. All HIV Positive Confirmed HIV Test Forms must be mailed to: Data Management, HIV Prevention Program, MS#11APV to the DPH within 7 days that the test results are available.
- Keep copies of all submitted paperwork in your files for your records

Specimen Collection, Storage and Transport Procedures

The CTDPH Laboratory will provide the following supplies free of charge to sites funded by DPH. Contact the CTDPH Laboratory Scientific and Support Services Section, Outfit Area {Ph: {860) 920-6674; Fax: {860) 920-6710}.

Associated Testing Forms:

- CTDPH Laboratory Clinical Test Requisition Form. Forms can be downloaded at: http://www.ct.gov/dph/lib/dph/laboratory/labhome/forms/clinical_test requisition_ol 9b_fill.pdf
- DPH Lab submitter address/account labels

Specimen Collection and Transport Outfits:

- For serum or plasma specimens: Vacutainer tube, plastic zip-lock baggie, silver inner sleeve, outside mailer sleeve, brown envelope.

Specimen Storage and Holding Times:

- Serum or plasma specimens; after collection, store refrigerated. Specimens may be transported to the laboratory at ambient temperature and **must be received by the laboratory within 21 days of collection.**

Reporting Results

- Currently the CT DPH laboratory is faxing results to HIV Testing Sites the same day the testing is completed (Results may also be phoned and then mailed if requested).

- **Unless other arrangements have been made, results will be faxed to the main site.**

GENERAL DATA ENTRY INSTRUCTIONS
HIV PREVENTION - PROGRAM REPORTING FORMS

Note: Using the "Tab Key" is the quickest way to move through the document. You do, however, always have the choice of using a mouse click to go into a certain field.

Date Fields
Date fields have been separated into a 2-digit month, 2-digit day, and 4-digit year. *(mm/dd/yyyy)*.

Phone Number Fields
Phone number fields have been formatted in such a way that they will auto format them into a (###) ###-####. It is only necessary for you to enter in the 10 digits of the phone number. There is no need to have parentheticals or the hyphen. Upon tabbing out of the field, the number should put the parentheticals and hyphen in for you.

Text Fields
Text fields are formatted in different ways throughout the document depending on what is being asked for that section. In most cases the length of the text fields will be set to "unlimited" so that narrative can be typed in. It is also important to know that when filling out narrative areas the field will continue to grow as you continue to type. When it reaches the end of a line it will go to the next line. You may see it push certain sections down the page. This is normal and, unfortunately, not easily preventable.

Also, you can still use the "enter button" to add lines / space between paragraphs. If you need to put a bullet into your narrative I would recommend using a "*****", "**-**", "**^**", or "**+**" to show distinctions.

General Number Fields
Number fields (like text fields) are formatted in certain ways depending on what is being asked. For example, percentage areas are limited to a 3-digit number (100% for example). Other areas such as Phone Extension will be limited to 4-5 digits. Brochures, Pamphlets, or any areas asking for quantities are also limited to 4-5 digits.

Check Boxes
Check boxes can be selected/de-selected either by clicking on the box or by pressing the space bar.

Calculating Fields
Fields set up with formulas, like those on the Target Population Forms, should self-calculate upon tabbing out of the fields. After entering a number and pressing "Tab key" to go to the next field, the calculation for the prior field should occur. It can be a little tricky deleting a number out of the calculating fields due to the small font so you will have to be a little diligent with that.

If you notice any discrepancies or errors in the calculations please contact: Susan Major at: (860) 509-7821. Thank you!

State of Connecticut
Department of Public Health
TB, HIV, STD, & Viral Hepatitis Program - HIV Prevention Programs

Contractor Name:

Contract Log#: -
(The Contract Log# is located in the upper right corner of your contract)

Tri-annual Reporting Period: ☐ **1st** (January to April) ☐ **2nd** (May to August) ☐ **3rd** (September to December)

HIV Prevention Program:

Component Category: (check all that apply)

☐ DEBI/EBI ☐ Drug User Health (*SSPs*) ☐ RTS- PrEP Navigation

☐ OTL – PrEP Navigation & [☐Couples HIV Testing and Counseling ☐ Social Network Strategies]

Program Reports:

☐ Intervention Forms

☐ Program Implementation Plan (due with first quarter report only)

☐ EvaluationWeb Report (Click on PDF icons to view EvaluationWeb reports instructions)

☐ neo360 Report (SSPs)

☐ **Other Report** (specify): _____

Report Submitted By: Full Name:

Title:

Phone#: Ext:

Submission Date: / / *(mm/dd/yyyy)*

Please include original and 1 copy of each report

Send Reports To:

Department of Public Health
HIV Prevention Reporting Forms
410 Capitol Avenue
P.O. Box 340308, MS# 11APV
Hartford, CT 06134-0308

Revised 12/27/2018 SM RRS

HIV Prevention Reporting Forms

Tri-annual Reporting Period: ☐ **1st** (January to April) ☐ **2nd** (May to August) ☐ **3rd** (September to December)

Person Completing Report/Contact Person:

Phone#: Ext:

Contractor Name:

Total Number of unduplicated patients who visited your agency for testing services in *this* trimester:
Total Number of HIV test events in *this* trimester:
Total Number of HIV positive test events in *this* trimester:
Total Number of HCV test events in *this* trimester:
Total Number of HCV positive test events in *this* trimester:
Total Number of unduplicated HIV negative test events in *this* trimester:

Condoms

Address of Condom Distribution Location	Contact Person	Town	Zip Code	Num. Distributed

Activities

Materials Distributed	Brochures	Total Condoms	Lubricants
Number (#) of Items distributed			
Number (#) of PrEP Materials distributed	Material Type: Amount: Material Type: Amount: Material Type: Amount:		
Number (#) of Linkages Made (HIV Negatives)			
Overdose Prevention/Naloxone Distribution			
EBI/DEBI			
Hepatitis C Screen			
HIV Testing			
Mental Health Services			
Non-Occupational Post-Exposure Prophylaxis (nPEP)			
Post-Exposure Prophylaxis (PEP)			
Pre-Exposure Prophylaxis (PrEP)			
Insurance Enrollment			
STD Screen & TX			
Substance Use TX			
Drug User Health (SSP)			
Domestic violence programs			
Sexual assault programs			
Other (Specify):			
Total Number of HIV Negatives linked to services:			
Number (#) of Linkages Made (HIV Positives)			
Overdose Prevention/Naloxone Distribution			
EBI/DEBI			
HIV Medical Care			
Medical Case Management			
Mental Health Services			
Partner Services			
STD Screen & TX			
Hepatitis C Screening			
TB Screening			
Substance Use TX			
Drug User Health (SSP)			
Domestic violence programs			
Sexual assault programs			
Other (Specify):			
Total Number of HIV Positives linked to services:			

Notes:

MEDICAL BILLING FOR HIV/HCV AND PrEP (IF APPLICABLE)

1. List number of patients not able to enroll in PrEP due to insurance issues:

2. Describe any insurance or payment related barriers to HIV screening, PEP, PrEP and/or HCV service delivery:

3. Does your healthcare setting bill for PrEP Counseling Services provided by non-clinical staff?
   YES ☐ **NO** ☐

Of all testing events in the tri-annual reporting period, please indicate the # of Rapid Tests used and the # of conventional blood draws done:

# of RAPID: _____

# of CONVENTIONAL: _____

# of 3rd PARTY REIMBURSEMENTS: _____

# of 3rd PARTY REIMBURSEMENT DENIALS: _____

Please list reason for denials, if any. Additional comments regarding the billing process can also go in this location.

Comments:

This section gives you a concise area for you to **list out specific program successes**.

	Successes
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

This section gives you a concise area for you to list out specific challenges your program is facing. If you've come up with resolutions to those challenges or if you have (possible resolutions) please feel free to list them below.

If you are not facing any challenges, please check the '*Not Applicable'* checkbox.

Not Applicable ☐

	CHALLENGES	RESOLUTIONS
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

NARRATIVE: Please comment on new initiatives, special events, issues impacting program implementation, materials developed for social marketing purposes, surveys conducted. Please include findings/results and attach any materials created for social marketing with your reports. **Reminder**: any materials must be approved by DPH Review Committee prior to use.

(Please use extra pages if needed)

Outreach Report

Outreach Venue*	Outreach Type	Person Conducting Outreach (Initials)	Number of people reached	Priority Population
	☐ - Online ☐ - Group ☐ - One-on-one			
	☐ - Online ☐ - Group ☐ - One-on-one			
	☐ - Online ☐ - Group ☐ - One-on-one			
	☐ - Online ☐ - Group ☐ - One-on-one			
	☐ - Online ☐ - Group ☐ - One-on-one			
	☐ - Online ☐ - Group ☐ - One-on-one			
	☐ - Online ☐ - Group ☐ - One-on-one			
	☐ - Online ☐ - Group ☐ - One-on-one			
	☐ - Online ☐ - Group ☐ - One-on-one			
	☐ - Online ☐ - Group ☐ - One-on-one			
	☐ - Online ☐ - Group ☐ - One-on-one			
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	☐ - Online ☐ - Group ☐ - One-on-one			
	☐ - Online ☐ - Group ☐ - One-on-one			
	☐ - Online ☐ - Group ☐ - One-on-one			

Note. * = Please describe outreach venue e.g., App name, Street and town name, Business name, School, Event, Medical setting, etc.

TRAINING/WEBINAR LOG

Staff Name	Name of Training	Training Type		Date of Training *(mm/dd/yyyy)*
		Training	Webinar	
		☐	☐	/ /
		☐	☐	/ /
		☐	☐	/ /
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Department of Public Health
TB, HIV, STD & Viral Hepatitis Section
HIV Prevention Unit

410 Capitol Avenue, MS# 11APV, PO Box 340308, Hartford, CT 06134-0308
Telephone: (860) 509-7801 --- Fax: (860) 509-7853 or (860) 509-7855

New Employee Form

Directions: Please complete this form upon the hiring of new staff. Submit to DPH ***within one week*** of the hire date or as soon as possible.

Contractor's Name: _____

New Employee's Name: **Last Name , First Name M.I.**

Date of Hire: / / *(mm/dd/yyyy)*

Title of Position Filled:

Academic/Educational qualifications:

Funding components and hours/week for this DPH funded position:

HIV/AIDS Coordinator: _____ +

OTL-PrEP Navigation _____ +

EBI/DEBI _____ +

RTS-PrEP Navigation _____ +

Drug User Health (SSP) _____ +

OTL-Couples HIV Testing Counseling _____ +

OTL-Social Networks Strategies _____ +

* Other funding source _____ +

***** Name of "Other Funding Source(s): _____ +

Total hours per week: _____

Signature of Employee: _____
Signature *Date*

Signature of Program Manager/Coordinator: _____
Signature *Date*

Department of Public Health
TB, HIV, STD & Viral Hepatitis Section
HIV Prevention Unit

410 Capitol Avenue, MS# 11APV, PO Box 340308, Hartford, CT 06134-0308
Telephone: (860) 509-7801 --- Fax: (860) 509-7853 or (860) 509-7855

DPH Use Only

Date Received: _____ Form distributed to: _____

Comments: _____

Resignation/Termination of Services Form

Directions: Please complete this form upon the termination/resignation of staff. Submit to DPH within one week of the hire/termination date. Submit to DPH ***within one week*** of resignation of position or as soon as possible.

Contractor's Name: _____

Employee's Name: **Last Name , First Name M.I.**

Resignation Submitted (check one): Yes ☐ No ☐

Date Submitted: / / *(mm/dd/yyyy)*

Date services were terminated: / / *(mm/dd/yyyy)*

Funding components and **hours/week** for this DPH funded position:

HIV/AIDS Coordinator: _____ +

OTL-PrEP Navigation _____ +

EBI/DEBI _____ +

RTS-PrEP Navigation _____ +

Drug User Health (SSP) _____ +

OTL-Couples HIV Testing Counseling _____ +

OTL-Social Networks Strategies _____ +

* Other funding source _____ +

***** Name of "Other Funding Source(s): _____ +

Total hours per week: _____

Signature of Employee: _____
Signature *Date*

Signature of Program Manager/Coordinator: _____
Signature *Date*

Revised 10/4/2018 SM RRS

Patient Navigation TRACKING FORM FOR HIV POSITIVE CLIENTS

Tri-annual Reporting Period: ☐ 1st (January to April) ☐ 2nd (May to August) ☐ 3rd (September to December)

Note: Please report separately for each referral for medical care, medical case management, partner services, and other referrals to services separately. Please report in Narrative any cases lost to follow up and actions taken to find patient.

DATE client was referred by Prevention Provider *(mm/dd/yyyy)*	UNIQUE CLIENT IDENTIFIER**	REFERRAL TO	DATE client was Linked / Seen by provider *(mm/dd/yyyy)*	Comments/Outcomes (If No Show, please describe follow up taken)	Is patient still linked with provider in 30 days?	Is patient still linked with provider in 60 days?	Is patient still linked with provider in 90 days?
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				

Patient Navigation TRACKING FORM FOR HCV POSITIVE CLIENTS

Tri-annual Reporting Period: ☐ 1st (January to April) ☐ 2nd (May to August) ☐ 3rd (September to December)

Note: Please report separately for each referral for medical care, and other referrals to services separately.

DATE client was referred by Prevention Provider *(mm/dd/yyyy)*	UNIQUE CLIENT IDENTIFIER**	REFERRAL TO	DATE client was Linked / Seen by provider *(mm/dd/yyyy)*	Comments/Outcomes (If No Show, please describe follow up taken)	Is patient still linked with provider in 30 days?	Is patient still linked with provider in 60 days?	Is patient still linked with provider in 90 days?
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				

Instructions for completing TRACKING FORM

Patient Navigation TRACKING FORM FOR HIV POSITIVE CLIENTS

HIV Prevention Program: ☐ HCV ☐ HIV

Tri-annual Reporting Period: ☐ 1st (January to April) ☒ 2nd (May to August) ☐ 3rd (September to December)

Note: Please report each referral for medical care, medical case management, partner services, and other referrals to services separately. Please report in Narrative all cases lost to follow up and actions taken to find patient.

DATE client was referred by Prevention Provider *(mm/dd/yyyy)*	UNIQUE CLIENT IDENTIFIER**	REFERRAL TO	DATE client was Linked / Seen by provider *(mm/dd/yyyy)*	Comments/Outcomes (If No Show, please describe follow up taken)	Is patient still linked with provider in 30 days?	Is patient still linked with provider in 60 days?	Is patient still linked with provider in 90 days?
04 / 10 / 2017	DLMN070273-2	Dr. Torres	No Show ☐ 04 / 20 / 2017		Yes	Yes	No, Contacted HIV DIS
04 / 11 / 2017	SEMJ061073-1	Dr. A. C.	No Show ☐ / /	Phone call made 4/12/17 Contacted HIV DIS 4/15/17			
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				

Note. ** = Unique Client Identifier -> First and Third letter of the First Name + First and Third of Last Name + date of birth (MMDDYY) + Gender: (1) Male, (2) Female, (3) Transgender Unknown, (4) MTF, (5) FTM, (6) Refused, (9) Unknown. This new client identifier will mirror the client identifier used in the CAREWare System (URN).

Sample Letter to No Shows

The following is a sample prompt for confidentiality tested clients who do not show for Post-Test Counseling. Please adopt this model into your agency's files.

Dear _____,

Please call the Health Department at (telephone number) for an appointment.

Thank you.

_____

Staff Name

OTL Counselor Protocol Checklist

Counselor Protocol Checklists
(Based on the CDC Guidance for HIV Prevention Counseling)

Pretest session:

Step 1: Introduce & orient the client

Purpose of session defined

- ❑ Client's motivation for counseling and testing assessed
- ❑ Source of referral assessed
- ❑ Outreach worker referral assessed

- ❑ Prior counseling and testing assessed / impact on behaviors assessed

- ❑ Knowledge assessment
  1. Assessment, not lecture
  2. Fill in gaps / misunderstandings
  3. Cover only information necessary for risk reduction and informed consent (unless the client wants more)

Step 2: Identify risk behaviors

- ❑ Sexual
- ❑ Drug use (especially IDU)
- ❑ Blood products
- ❑ Other

Step 3: Identify safer goal behaviors

- ❑ Sexual
- ❑ Drug use (especially IDU)
- ❑ Blood products
- ❑ Other

Step 4: Develop an action plan

Prevention recommendations that may be considered when developing the plan:

1. Behave as if HIV infected
2. Abstinence
3. Mutual monogamy
4. Limit sex partners
5. Condoms – Discuss correct technique. Hand out. Demonstrate with a model.
6. For IDU drug users:
   a. get off drugs
   b. do not share works
   c. use clean needles, etc.

Step 4a: HIV Test Decision Counseling

- ❑ Need for a test

- ❑ Meaning (for client) of test results assessed
- ❑ Potential impact of a negative or a positive test result on the client's life: coping skills, supports, and future behavior assessed
- ❑ Integrate HCV when appropriate

Partner Services discussed

- ❑ Current and past partners
- ❑ Importance of partner notification
- ❑ Waiting period plans / supports
- ❑ Discuss the window period
- ❑ Testing procedure (orasure, blood draw) described

Step 5: Make referrals, linkages & provide support

- ❑ Assess and prioritize with the client the need for referrals
- ❑ Drug treatment (for alcohol, non-injecting drug users, and IV drug users)
- ❑ Family planning services
- ❑ STD and TB services

Step 6: Summarize & close the session

- ❑ Recap action plan
- ❑ Demonstrate any risk reduction techniques

Confidential testing

- ❑ Confidential described as standard
- ❑ Discrimination discussed
- ❑ Informed consent
- ❑ Client read form or counselor reads form to client
- ❑ Confidential testing: client and counselor sign form

Return for posttest counseling

- ❑ Specific appointment made
- ❑ Follow-up plan for no show described to client

Closure

- ❑ Reinforcement of risk reduction plans
- ❑ Handouts
- ❑ Referrals
- ❑ Prepare for different counselor for post test, if necessary

Testing

- ❑ By counselor, or
- ❑ Client walked to drawing station

Post test session – seronegative

Purpose of session defined

Test results given

- Silence / opportunity for client to express emotions
- Exploration of the client's initial reaction to the test result
- Assess meaning of test result for the client / clarification of meaning
- Advice regarding retesting

Review and revision of risk reduction plan

Risk reduction guidelines reviewed

- Behave as if HIV infected
- Abstinence
- Mutual monogamy
- Limit sex partners
- Condoms – Discuss correct technique. Hand out. Demonstrate with a model.
- For drug users:
- get off drugs
- do not share needles
- use clean needles, etc.

Referrals

- Drug treatment / 12 step programs
- Family planning services
- STD and TB services

Discrimination discussion

Conclusion

- Handouts
- Referrals

Posttest session – seropositive

Purpose of session defined

Test results given

- ❑ Silence / opportunity for client to express emotions
- ❑ Exploration of client's initial reaction to test result
- ❑ Exploration of the meaning of the test result to the client
- ❑ Counselor clarification of the meaning of the test result
- ❑ Prioritizing of client's most immediate concerns
- ❑ Exploration of client coping and supports, suicide / homicide assessment

Risk reduction plan and guidelines reviewed:

- ❑ Status of personal risk reduction plan during the waiting period
- ❑ Avoid reinfection with other HIV and other STDs
- ❑ Abstinence
- ❑ Mutual monogamy
- ❑ Limit sex partners
- ❑ Condoms – Discuss correct technique. Hand out. Demonstrate with a model.
- ❑ For drug users:
- ❑ Offer treatment
- ❑ do not share works
- ❑ use clean needles, etc.

Additional guidelines for seropositives:

- ❑ do not donate blood, sperm, etc.
- ❑ avoid pregnancy
- ❑ do not breastfeed
- ❑ do not cause pregnancy
- ❑ clean blood spills
- ❑ cook food thoroughly

Specific plans for ongoing risk reduction

Referrals

- ❑ Early intervention / medical services including:
- ❑ Offer treatment
- ❑ family planning services
- ❑ STD and TB services
- ❑ psychological / social services
- ❑ secondary prevention services

Partner notification

- ❑ Strongly promote C.A.R.E.
- ❑ Specific plans for contract for client to contract present partner(s) and past partner(s)
- ❑ Discrimination discussion

Conclusion

- ❑ Handouts, condoms
- ❑ Reinforce referrals

Counselor Observation

Pre Test Counseling

- ❑ Is the counselor empathetic and able to develop rapport with the client? Are open-ended questions used routinely? Does the counselor acknowledge the client's strengths and give supportive affirmation to the client? Does the counselor demonstrate good reflective listening skills?

- ❑ Is the counseling culturally appropriate for the client population? Is the language appropriate? Is information given geared at the comprehension level of the client?

- ❑ Is the purpose of the session defined? Does the counselor assess the client's motivation for being tested and reason for visit? Is confidentiality assured?

- ❑ Is the session an interactive process between the client and the counselor as opposed to lecture or "form driven"?

- ❑ Does the risk assessment flow from the knowledge assessment? Is a thorough risk assessment conducted?

- ❑ Is the client's knowledge carefully assessed? Does the counselor then fill in knowledge gaps and correct understandings, or is the client lectured? Does the counselor give accurate information? Is the information covered limited to the matter at hand, or does the counselor digress?

- ❑ Does the counselor make clear specific and reasonable risk reduction plans with the client using appropriate risk reduction guidelines, especially for the waiting period? Is the process for developing risk reduction plans client centered? Are both long and short-term risk reduction goals addressed, with emphasis on concrete and specific short-term goals? Is the client offered the opportunity for building skills (e.g., condom and/or needle cleaning demonstration, role-playing, etc.)?

- ❑ Does the counselor assess the potential impact of positive and negative results on the client and the client's future behavior? Are clues gleaned from the client's manner of handling past crises?

- ❑ Does counselor assess the client's supports during the waiting period and offer resources?

- ❑ Does the counselor make a suicide / homicide assessment, as appropriate?

- ❑ Does the counselor strongly promote partner services for current and past partners? Does the counselor strongly promote return for results and describe follow-up procedures?

- ❑ Is confidential testing the standard and described as such by the counselor? If the client will not otherwise be tested, is anonymous testing offered by referral or on-site? Are the pros and cons of confidential and anonymous testing objectively discussed?

- ❑ Do the counselor and client go over the informed consent form? Is the form signed according to protocol?

- ❑ Is an appointment made for posttest counseling at the pre test visit?

- ❑ How carefully and completely is the HIV counseling and testing form filled out?

- ❑ Is phlebotomy readily accessible, and are universal precautions followed?

- ❑ Does the session come to a good closure (reinforcement of return, referrals, etc.)? Are handouts given?

- ❑ Does the counselor perform the test immediately, or is the client walked to the drawing station?

Post Test Counseling - observe both seronegative and seropositive post test sessions

- How carefully is the test result checked to ensure the correct result is being given to the client? Is the purpose of the session defined?

- During posttest counseling, does the counselor use silence as an opportunity to allow the client to deal with his or her initial reaction to the test result? Does the counselor allow the client to express his or her emotions?

- Is the session client centered? Does the counselor allow the client to prioritize the most important concerns to be dealt with during the post test session?

- Does the counselor reassess, reinforce, and update risk reduction plans as well as the client's knowledge base?

- Does the counselor reinforce risk reduction messages during the post test session?

- Does the counselor make a suicide / homicide assessment, as appropriate?

- Does the counselor make appropriate referrals to medical and social services and for additional risk reduction services (i.e., secondary prevention services)? How well are these referrals able to insure successful completion of the referrals?

- Does the counselor strongly promote the C.A.R.E. program to all seropositive clients? Does the counselor work at getting at least voice (preferable face-to-face) contact between C.A.R.E. counselor and the client? If the client refuses the C.A.R.E. program, are specific "contracts" drawn up between the client and the counselor for notification and counseling of the partners?

- How carefully and completely is the paperwork filled out?

- Does the session come to an appropriate closure? Are appointments / referrals reinforced?

TB, HIV, STD, and Viral Hepatitis Program-HIV Prevention Program
Outreach, Testing, and Linkage (OTL) Services
Site Visit Observation & Chart Audit Tool

Instructions:

1. The **Contract Manager** will use the Department of Public Health (DPH) OTL Site Visit Tool (Attachment 1) to mark "**Yes**" or "**No**" to indicate whether the OTL staff are in compliance with policy and procedures for OTL Services.
    a. The Contract Manager must be familiar with contractual requirements, in addition to the implementation plan submitted by the agency for OTL services required under contract with DPH for the provision of HIV Prevention Services.
    b. The tools must be completed at a minimum of once a year during scheduled site visits with the agency.
    c. Whenever assessing the site as "**No**", the Contract Manager should provide recommendations for improvements in the Action Plan Section of the report (**VIII. ACTION PLAN & RECOMMENDATIONS**).
    d. Conclusions should be based on the consistency for which the site meets DPH contractual requirements and policies.
    e. The Observation Tool (Attachment 2) should be used to assess OTL skills during an observational session with OTL staff. The Chart/Record Audit Tool (Attachment 3) should be used to assess chart/medical record compliance. Contract Managers must randomly select charts/medical records from the previous reporting period. Charts with less than 70% (Not Met) will require a Corrective Action Plan to address deficiencies from the chart review. The chart review form can record up to Ten (10) client records. Use additional forms if needed.
2. The DPH requires that each program with one or more deficiencies will file a **Corrective Action Plan** listing the steps that the program will take to correct those deficiencies. The citation of deficiencies, and the corrective action process, can work as aids to programs in focusing resources in specific areas in a process of continuous improvement.
    a. **Corrective Action Plan**: The program will file a plan for the correction of those deficiencies with their Contract Manager within 10 business days of receipt of the DPH Site Visit Letter. The Corrective Action Plan should cite each deficiency and the plan for correcting that deficiency. The plan needs to be verifiable, i.e. what documentation can the program submit that will verify that the deficiency is corrected
3. **Follow-up**: The DPH must offer training and technical assistance, if appropriate, to help contractors correct identified deficiencies or failures to meet DPH requirements. Technical assistance may be offered concurrently with the notification of a deficiency or deficiencies and should focus on the specific issues of the agency to the extent possible.
4. The completed summary report letter should be summarized and disseminated to the agency no more than thirty (30) business days from the day of the initial site visit. If a corrective action plan has been issued, the agency must respond to the plan within ten (10) business days of the receipt of the plan. The Contract Manager will follow-up with agency (site visit) within three (3) months to ensure that the action items from the corrective action plan have been addressed. A template Site Visit Summary Report letter with instructions is attached at the end of this audit tool.
5. Date & File Copy.

Attachment 2
Observation Tool

TB, HIV, STD, and Viral Hepatitis Program-HIV Prevention Program
Outreach, Testing, and Linkage (OTL) Services- Observation Tool

Contractor:
OTL Provider:
Contract Manager: **Date:**

OTL Staff Performance Evaluation *(Complete the following elements per OTL Observed)*			**Session # ____ observed DPH** **Session #____by OTL Supervisor**
Met	**Not Met**	**NA**	**OTL Standards**
Introduce/orient client (Step 1)			
☐	☐	☐	Introduce him/herself by name
☐	☐	☐	Explain role
☐	☐	☐	State duration of session
☐	☐	☐	Explain test options
☐	☐	☐	Explain procedures
Provide information			
☐	☐	☐	Test benefits
☐	☐	☐	Test results
☐	☐	☐	Importance of results
☐	☐	☐	HIV risk and transmission
Obtain Informed Consent			
			Determine if client understood the written consent
☐	☐	☐	Client signed off on informed consent
Assess client readiness			
☐	☐	☐	Readiness to receive test results the same day
☐	☐	☐	Assess support systems
☐	☐	☐	Assess reactions to results (emotional and mental status)
Conduct the test			
☐	☐	☐	Explain the testing process
☐	☐	☐	Appear organized
☐	☐	☐	Follow HIV Rapid Test procedures
☐	☐	☐	Complete labeling
☐	☐	☐	Documentation
☐	☐	☐	Use safety precautions
Identify current risk behaviors and circumstances (while test is processing). (Step 2)			
☐	☐	☐	Sex or needle-sharing partner (s)
☐	☐	☐	Circumstances
☐	☐	☐	Timeframes
Identify safer goal behaviors that the client is willing to adopt. (Step 3)			
☐	☐	☐	Identify behaviors:
☐	☐	☐	Interpreted results
☐	☐	☐	Reported test results
☐	☐	☐	Meaning of results
☐	☐	☐	Discussed importance of confirmatory test when applicable
☐	☐	☐	Discussed the importance of the need to retest if applicable (window period)
Identify a personal action plan (Step 4)			
☐	☐	☐	Discussed and offered PrEP
☐	☐	☐	Plan is realistic for client
☐	☐	☐	Action Steps included
			Follow-up plan included

Provide support and referrals (Step 5)			
☐	☐	☐	Assess the client's referral needs
☐	☐	☐	Made appropriate referrals:
☐	☐	☐	Facilitated an active referral
☐	☐	☐	Documented the referral(s) (PrEP Acuity Form)
☐	☐	☐	Follow-up plan included
Summarize and close the session (Step 6)			
☐	☐	☐	Ask client for questions or comments
☐	☐	☐	Summarize the action plan
☐	☐	☐	Summarize the referral plan
☐	☐	☐	Offered support
Overall Quality			
☐	☐	☐	Did staff keep the session focused on HIV risk reduction
☐	☐	☐	Use of open-ended questions
☐	☐	☐	Did staff give information simply and in a manner that the client understood?
☐	☐	☐	Did the client provide skill building or harm reduction opportunities for the client when appropriate?

Comments:

OTL and PrEP Navigation

CHART AUDIT FORM - 10 Charts per Quarter

Attachment 3
Chart Audit Tool

Minimum of 10 charts or all charts if less than 10. At least 3 of the 10 charts should be HIV positive clients, or all positive files if less than three.											
OTL Standard ↓ Record/Chart Number →											**Overall % Met**
Completeness of Chart											
Documentation of Client Identifying information (client name, unique identifier/code, are listed on all forms/records in chart											
Documentation of required CDC EvaluationWeb Test Forms											
Signed consent form in chart											
Documentation of Risk Assessment											
Documentation of Psychosocial Assessment											
All referrals are documented (type of referral, confirmation, including documentation when not applicable, or Referrals and Linkage forms)											
Copy of HIV Test Result in chart											

Copy of CDC HIV Test Forms											
Core Elements											
Clients perception of his/her own risk for HIV/STD/HCV risk											
Documentation of Client readiness to test (impact & sources of support)											
Pattern of risk behavior/risk triggers (Action Plan-benefits and barriers addressed)											
Documentation of recent risk exposure (window period discussed)											
Documentation of attempts to Follow-up with client and providers (if applicable) regarding the outcome of referrals or for clients who fall out of care (telephone calls, f/up letters)											
PrEP Screening/Assessment											
Addresses behaviors related to HIV/STD/HCV risk											
Pattern of risk behavior/risk triggers (PrEP Risk Reduction Plan-benefits and barriers addressed)											
Documentation of readiness for PrEP Services (Completed PrEP Acuity Form)											
PrEP Intake											
Documentation of HIV Risk											
Documentation of active linkages for clients who require social or financial support services not previous identified at intake											
Assessment of Social Determinants of Health (SDH)											

PrEP Health Care Navigation											
Documentation of follow up within one week of initial PrEP clinical appointment											
Documentation of support with medication adherence											
Documentation of assisting clients obtaining and enrolling them into financial resources (public or marketplace health insurance plans)											
PrEP Maintenance											
Documentation of regular screening at 1 month and three months											
Documentation of periodic re-assessment of risk											
Documentation of follow-up activities (face to face encounters, client phone consultations)											
Documentation of additional referrals and linkages is applicable											
Documentation of attempts to Follow-up with client and providers (if applicable) regarding clients who fall out of care (telephone calls, f/up letters)											
For HIV Positive (+) charts only											
Documentation of Partner Services referral, linkage, and outcome of referral to DIS worker (required for contractual sites)											

Documentation of HIV + results											
Documentation of HIV Confidential Case Report Form (CRF) Surveillance program											
Documentation of HIV Incidence											
Evidence of Referral Documentation (includes assessment of need, referral forms, type of referral (passive or active), linkages made etc.)											
Documentation of outcomes of referrals made to HIV Care, Medical Case Management, Partner Services/ DIS, etc.											
Documentation of attempts to Follow-up with client and providers (if applicable) regarding the outcome of referrals (telephone calls, f/up letters)											
Key: 100 –95% M= Met 94-70% PM= Partially Met 69-0% NM=Not Met NA= Not applicable											
100%-70 %(Met & Partially Met) and higher for adherence to CDC standards for HIV OTL ***69%-Less requires Corrective Action Plan to which agencies must respond to within 10 of the receipt of the report.***											

Cc: Prevention Supervisor
Contract Manager
Agency Executive Director

CLIENT REFERRAL FORM FOR PARTNER SERVICES

CONNECTICUT DEPARTMENT OF PUBLIC HEALTH STD CONTROL PROGRAM

ATTN:_____ DATE:_____

AGENCY/ORGANIZATION INFORMATION

REFERRAL SITE (NAME): _____

☐ DOC ☐ ETI ☐ EIS ☐ MCM ☐ OTL ☐ OTHER: _____

PERSON REFERRING (NAME & TITLE): _____

PHONE NUMBER: _____ E-MAIL: _____

REASON FOR REFERRAL

☐ Newly diagnosed HIV client, diagnosed within the last 12 months. **List A#:** _____

Client was infected more than 12 months ago and:

☐ Has a new reportable STD diagnosis, infected within the last 3 months.

☐ Unprotected sex within the last 3 months with multiple partners and/or anonymous partner(s) and/or new partner(s).

☐ Known partners are unaware of the client's status, client is having sex after HIV diagnosis.

☐ Client is requesting partner services for a new partner.

CLIENT INFORMATION (complete all of the information below)

NAME (LAST, FIRST): _____ DOB: _____

GENDER: ☐ M ☐ F ☐ MTF ☐ FTM ☐ Unk PRIMARY LANGUAGE: _____

MARITAL/RELATIONSHIP STATUS: ☐ S ☐ M ☐ Div ☐ Sep ☐ W ☐ Cohab ☐ Unk

ETHNICITY: ☐ Hispanic ☐ Not Hispanic

RACE (check all that apply): ☐ Am. Indian/Alaska Native ☐ Asian ☐ Black/African Am.
☐ Native Hawaiian/Other PI ☐ White ☐ Unk

STREET ADDRESS: _____

CITY/TOWN STATE ZIP CODE

PHONE NUMBERS (home/cell): _____ E-MAIL: _____

WEBSITES/PHONE APPS: _____

PHYSICAL DESCRIPTION: _____

GENDER OF SEX PARTNERS (check all that apply): ☐ M ☐ F ☐ MTF ☐ FTM ☐ Unk

RISK FACTORS: ☐ MSM ☐ IDU ☐ Exchanges sex for drugs or money
☐ Other: _____

DATE OF HIV DIAGNOSIS: _____ DATE OF LAST NEGATIVE HIV TEST: _____

HIV Medical Care Physician: _____ **Phone #**: _____

If DOC Referral, what is the earliest date this client may be released from custody? _____

If information on partners is available, complete page 2, Partner Referral form for Partner Services for each partner.

***Note:* Prior to sending any fax, please contact and speak directly to a Disease Intervention Specialist Supervisor - Region 1: Ava Nepaul (860) 509-8239 or Region 2: Wanda Richardson (203) 946-7233. Fax completed forms to Ava Nepaul at (860) 509-7275 or Wanda Richardson at (203) 946-2950.**

DO NOT E-MAIL THIS FORM.

PARTNER REFERRAL FORM FOR PARTNER SERVICES

CONNECTICUT DEPARTMENT OF PUBLIC HEALTH STD CONTROL PROGRAM

ATTN:_____ DATE:_____

AGENCY/ORGANIZATION INFORMATION

REFERRAL SITE (NAME): _____

☐ DOC ☐ ETI ☐ EIS ☐ MCM ☐ OTL ☐ OTHER: _____

PERSON REFERRING (NAME & TITLE): _____

PHONE NUMBER: _____ E-MAIL: _____

PARTNER INFORMATION (complete all of the information below)

NAME (LAST, FIRST): _____ DOB: _____

GENDER: ☐ M ☐ F ☐ MTF ☐ FTM ☐ Unk PRIMARY LANGUAGE: _____

MARITAL/RELATIONSHIP STATUS: ☐ S ☐ M ☐ Div ☐ Sep ☐ W ☐ Cohab ☐ Unk

ETHNICITY: ☐ Hispanic ☐ Not Hispanic

RACE (check all that apply): ☐ Am. Indian/Alaska Native ☐ Asian ☐ Black/African Am.
☐ Native Hawaiian/Other PI ☐ White ☐ Unk

STREET ADDRESS: _____

CITY/TOWN STATE ZIP CODE

PHONE NUMBERS (home/cell): _____ E-MAIL: _____

WEBSITES/PHONE APPS: _____

PHYSICAL DESCRIPTION: _____

RISK FACTORS: ☐ MSM ☐ IDU ☐ Exchanges sex for drugs or money
☐ Unaware of Client's status ☐ Other: _____

EXPOSURE TYPE(S):
Check all that apply in the table below and complete information about each type of exposure this Partner had to the Client (see page 1, *Client Referral Form for Partner Services*).

Exposure Information	☐ *Sex*	☐ *Syringe/ works sharing*	☐ *Other, specify:*
Date first contact (mm/dd/yyyy)			
Date last contact (mm/dd/yyyy)			
Frequency (e.g., two times per week)			

COMMENTS: _____

_____

_____

_____

***Note:* Prior to sending any fax, please contact and speak directly to a Disease Intervention Specialist Supervisor - Region 1: Ava Nepaul (860) 509-8239 or Region 2: Wanda Richardson (203) 946-7233. Fax completed forms to Ava Nepaul at (860) 509-7275 or Wanda Richardson at (203) 946-2950.**

DO NOT E-MAIL THIS FORM.

Rapid HIV Test Results Log

Client ID*	Test Area Temp	Date/Time Specimen Collected	Specimen Type	Divided Pouch Lot #	Divided Pouch Exp Date	Test Start Time	Test Read Time	Test Result	Tester	Date /Time Result Reported to Client	Confirmatory Testing				Reviewed by and date
											Tracking #	Specimen Type (blood or oral fluid)	Test Result	Date Result Reported to Client	

* Unique 1D number assigned to client

For Trainer Use:

Performance:

- ❑ Pass
- ❑ Needs additional instruction and practice before testing clients

Comments:_____

_____

Trainer: _____ Date:_____

Sharps Injury Log

Date	Location Injury Occurred	Brief description of how the injury occurred (procedure being done, action being performed-fingerstick, venipuncture, waster-disposal include area of the body injured	Type of Device (lancet, syringe, etc.)	Brand Name of Device

OSHA's Bloodborne Pathogens Standard requires an employer to establish and maintain a Sharps Injury Log for recording all punctures of skin occurring from contaminated sharps. The purpose of the Log is to aid in the evaluation of devices being used in healthcare and other facilities and to identify devices or procedures/techniques requiring additional attention or review. This Log must be kept in addition to the Injury and Illness Log required by OSHA. The Sharps Injury Log should not list the names of affected employees (to maintain confidentiality) but, at a minimum, it should contain the type and brand of device involved in the incident, the department or work area where the exposure incident occurred, and an explanation of how the incident occurred. The Log should include all sharps injuries occurring in a calendar year and it must be retained for 5 years following the end of the year to which it relates.

Temperature Log:

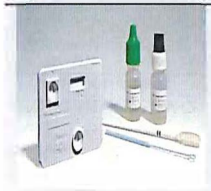
Name of Facility: _____

To be recorded at the beginning of each workday. Temperature Range: _____

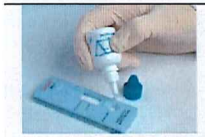
Date	°F	Initials	Corrective Action if Needed

Date	°F	Initials	Corrective Action if Needed

Rapid HIV Tests Suitable for Use in Non-Clinical Settings (CLIA-waived)

Test Name	Time to test result	Indications for use	Sensitivity for established HIV-1 infection, % (95% CI)[b]	Specificity % (95% CI)[b]	CLIA-Waived approved specimen types and volumes	Test kit shelf life/ storage temperature range/Testing area temperature range	Manufacturer web site
 **Chembio DPP HIV-1/2**	Blood: between 10 and 25 min Oral fluid: 25-40 min for reactive results and 40 min for non-reactive results	Antibodies to HIV-1 and 2	Finger stick whole blood 99.8 (99.2-99.9) oral fluid 98.9 (98.0-99.4) Venous whole blood 99.9 (99.4-99.9)	Finger stick whole blood 100 (99.8-100) oral fluid/ venous whole blood 99.9 (99.7-99.9)	Finger stick or venous whole blood 10 µl Or oral fluid swab	23 months; 36 to 86°F / 64 to 86°F	http://chembio.com/products/human-diagnostics/dpp-hiv-12-assay/
 **Clearview COMPLETE HIV 1/2**	15 min	Antibodies to HIV-1 and 2	Finger stick or venous whole blood 99.7 (98.9-100.0)	Finger stick or venous whole blood 99.9 (99.6-100.0)	Finger stick or venous whole blood 2.5 µL	24 months; 46 to 86°F/ 64 to 86°F	http://www.alere.com/en/home/product-details/clearview-complete-hiv-1-2.html
 **Clearview HIV 1/2 STAT-PAK**	15 min	Antibodies to HIV-1 and 2	Finger stick or venous whole blood 99.7 (98.9-100)	Finger stick or venous whole blood 99.9 (99.6-100.0)	Finger stick or venous whole blood 5 µL	24 months; 46° to 86° F/ 64 to 86°F	http://chembio.com/products/human-diagnostics/hiv-12-stat-pak-assay/

Test Name	Time to test result	Indications for use	Sensitivity for established HIV-1 infection, % (95% CI)[b]	Specificity % (95% CI)[b]	CLIA-Waived approved specimen types and volumes	Test kit shelf life/ storage temperature range/Testing area temperature range	Manufacturer web site
 **Determine HIV-1/2 Ag/Ab Combo Test**	20 min	Antibodies to HIV-1 and HIV-2, Detects HIV-1 p24 Antigen	Finger stick whole blood 99.9 (99.4-100)	Finger stick whole blood: Low risk subjects 100 (99.5-100), High risk subjects 99.7 (98.9-100)	Finger stick whole blood 50 µL	15 months; 36-86°F/ 59-86°F	http://www.alere.com/en/home/product-details/determine-1-2-ag-ab-combo-us.html
 **INSTI HIV-1/HIV-2 Antibody Test**	<2 min	Antibodies to HIV-1 and 2	Finger stick whole blood 99.8 (99.3-99.9)	Overall from low, high and unknown risk individuals Finger stick whole blood 99.5 (99.0.9-99.8)	Finger stick whole blood 50 µl	15 months; 59-86°F/ 59-86°F	http://www.biolytical.com/products/instiHIV
 **OraQuick ADVANCE Rapid HIV-1/2 Antibody Test**	20 min	Antibodies to HIV-1 and 2	Oral fluid 99.3 (98.4-99.7) finger stick whole blood (venous whole blood not evaluated) 99.6 (98.5-99.9)	Oral fluid 99.8 (99.6-99.9), finger stick whole blood (venous whole blood not evaluated) 100 (99.7-100)	Finger stick or venous whole blood 5µl or oral fluid swab	12 Months; 36-80°F/ 59-99°F	http://www.orasure.com/products-infectious/products-infectious-oraquick.asp

Test Name	Time to test result	Indications for use	Sensitivity for established HIV-1 infection, % (95% CI)[b]	Specificity % (95% CI)[b]	CLIA-Waived approved specimen types and volumes	Test kit shelf life/ storage temperature range/Testing area temperature range	Manufacturer web site
 **Uni-Gold Recombigen HIV-1/2**	10 min	Antibodies to HIV-1 and HIV-2	Finger stick or venous whole blood 100 (99.5-100.0)	Finger stick or venous whole blood 99.7 (99.0-100)	Finger stick or venous whole blood 50 µL	12 months; 35.6-80.6°F/ 59-80.6°F	http://www.trinitybiotech.com/area/uni-gold/

[a] CLIA-waived rapid tests can be used in settings such as: community-based organizations, field testing, outreach activities, STD or other clinics, mobile clinics, non-traditional testing, or community/college clinics. The Clinical Laboratory Improvement Amendments (CLIA) sets criteria based on complexity levels of tests. Briefly, there are three levels of complexity: 1) Waived – simple, low-risk tests that can be performed with minimal training that do not require centrifugation of specimens for testing, 2) Moderate Complexity – simple tests that use plasma or serum specimens (must participate in an external proficiency testing program), 3) High Complexity – tests that require trained laboratory personnel, involve multiple-step protocols, frequent quality control, and participation in an external proficiency testing program. For more information about CLIA regulations go to Link to CLIA Regulations.

[b] Sensitivity is a measure of the test's ability to correctly identify persons with a disease. Specificity is the test's ability to correctly identify persons without the disease.

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Counseling Concepts and Skills

3 Selected Counseling Concepts

1. Focus on Feelings

In successful helping interactions, the focus must first be placed on how the client feels.

Until the counselor attends the client's feelings, the client will not hear much of what the counselors says.

Be willing to bring up, listen to, and respond to the client's feeling-level reactions, beliefs, and issues.

2. Manage your Own Discomfort

Examine and know your own values and seek to understand how others feel.

Recognize your discomfort and manage it- don't let it become a barrier to communication with the client.

3. Set Boundaries

Both the counselor and the client must be in charge of their own lives.

Don't allow the client to make the counselor's behavior the focus of the session.

Counselors should not assume responsibility for the client's behavior or expect to solve the client's problems - only the client can do these things.

4 Selected Counseling Skills

1. Open Ended Questions

Open-ended questions can't be answered with a simple "yes" or "no."

Be careful about using "why" questions- they may be perceived as threatening.

Use polite imperatives like "Tell me more about .... "

2. Attending

Show the client you are listening through positive verbal and non-verbal cues.

3. Offer Options, Not Directives

Giving directives sets up a power struggle between the counselor and the client.

Offer a "buffet" of all relevant options.

Avoid "You need to..." statements.

4. Give Information Simply

Offer the client information that is relevant to their life circumstances and their risk behaviors. Use terms and language the client can understand. It's okay to say, "I don't know."

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Decontamination - Large Blood Spill

A large blood spill is defined as equal to or greater than the contents of a small test tube ofblood. Large amounts of blood can inactivate bleach; therefore, it is very important to wash the area thoroughly with soap and water *before* applying bleach to a large blood spill. This will remove most of the blood and permit the bleach to decontaminate the area.

Large Blood Spill Clean up Procedure

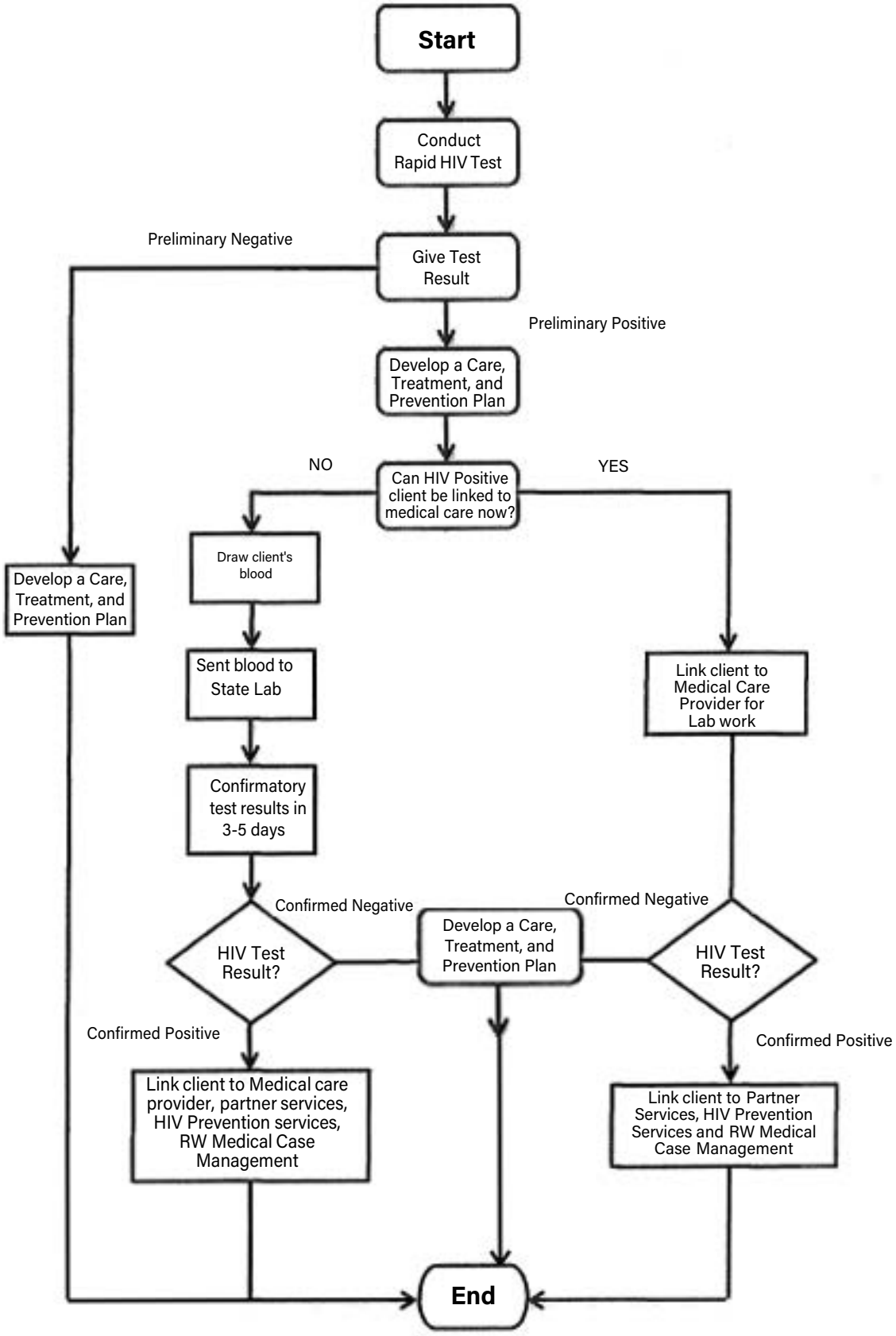
1. Wear gloves.
2. Identify the spill area.
3. Examine spill area for the-presence of any broken glass or other contaminated sharp objects.
4. Remove any contaminated sharps with a forceps, brush, and dustpan before proceeding with clean up.
5. Place any non-disposable items (forceps, brush, dustpan) used to remove contaminated sharps in a separate biohazard container for future decontamination. Label for decontamination, notify the appropriate person, and transport to the designated location.
6. Place absorbent paper towels on top of the spill and allow towels to absorb most of the liquid blood.
7. Carefully place towels in a biohazard bag.
8. Wash the area with soap and water, then wipe up with an absorbent towel.
9. Wipe up the area using absorbent towel.
10. Apply a 10% solution of household bleach (or an EPA-registered disinfectant effective against HBV, HIV, and other bloodborne pathogens) to the work surface.
11. Let the bleach solution stand 2-3 minutes.
12. Wipe up the area using an absorbent towel.
13. Dispose of the towels in a biohazard bag.
14. Remove gloves using the appropriate technique.
15. Dispose of gloves in a biohazard bag.
16. Wash hands.
17. Shut off faucet using towel.
18. Decontaminate the sink and work areas before leaving.

DPH HIV Prevention Interventions
January 2019 to December 2021

1.	**Routine Testing Services with PrEP Navigation** Expanded and Integrated HIV testing occurs in health care settings that serve populations with a high prevalence of HIV to conduct routine HIV screening in community health centers, hospital emergency departments and outpatient clinics. In addition, PrEP Navigation is a process of service delivery to help a person obtain timely, essential and appropriate PrEP-related medical and social services to optimize his or her health and prevent HIV transmission and acquisition. **Funded Contractors:** • Anchor Health Initiative, Stamford, CT (203) 674-1102 & Hamden, CT (203) 903-8308 • Community Health Centers, Statewide (860) 347-6971 • Cornell Scott Hill Health Center, New Haven , CT (203) 503-3148 • Planned Parenthood, Statewide (203) 752-2821 • Prospect Waterbury, Waterbury , CT (203) 573-7228 • Southwest Community Health Center, Bridgeport, CT (203) 332-3162 • StayWell Health Center, Waterbury, CT (203) 756-8021 Ext. 3113 • CT Children's Medical Center, Hartford, CT (860) 466-9685 or (860) 466-0818. • Yale New Haven Hospital, New Haven, CT (203) 688-3184
2.	**Healthy Love** Healthy Love is a single-session, small-group (4-15 women) intervention delivered to pre-existing groups of black women (e.g., friends, sororities) in settings of their choosing. It delivers HIV prevention information and teaches condom use skills in a highly interactive, festive, and non-judgmental manner. **Funded Contractors:** • GBAPP, Inc., Bridgeport, CT (203) 366-8255 • APEX, Danbury, CT (203) 778-2437
3.	**MPowerment** MPowerment is a community level Intervention for young men who have sex with men (MSM). MPowerment uses a combination of informal and formal outreach, discussion groups, creation of safe spaces, social opportunities, and social marketing to reach a broad range of young gay men with HIV prevention, safer sex, and risk reduction messages. **Funded Contractors:** • A Place to Nourish your Health (APNH), New Haven, CT (203) 624-0947 • Hartford Gay and Lesbian Health Collective, Hartford, CT (860) 278-4163
4.	**NIA** *Nia* is a video-based motivational skills-building small-group intervention consisting of 6-10 participants in each group. The intervention includes videos, movie clips, and discussion to educate men about HIV/AIDS, elevate their mood, and entertain them while reinforcing information and motivating behavior change. **Funded Contractors:** • AIDS CT, Hartford, CT (860) 247-2437 • InterCommunity, Inc., East Hartford, CT (860) 461-0130

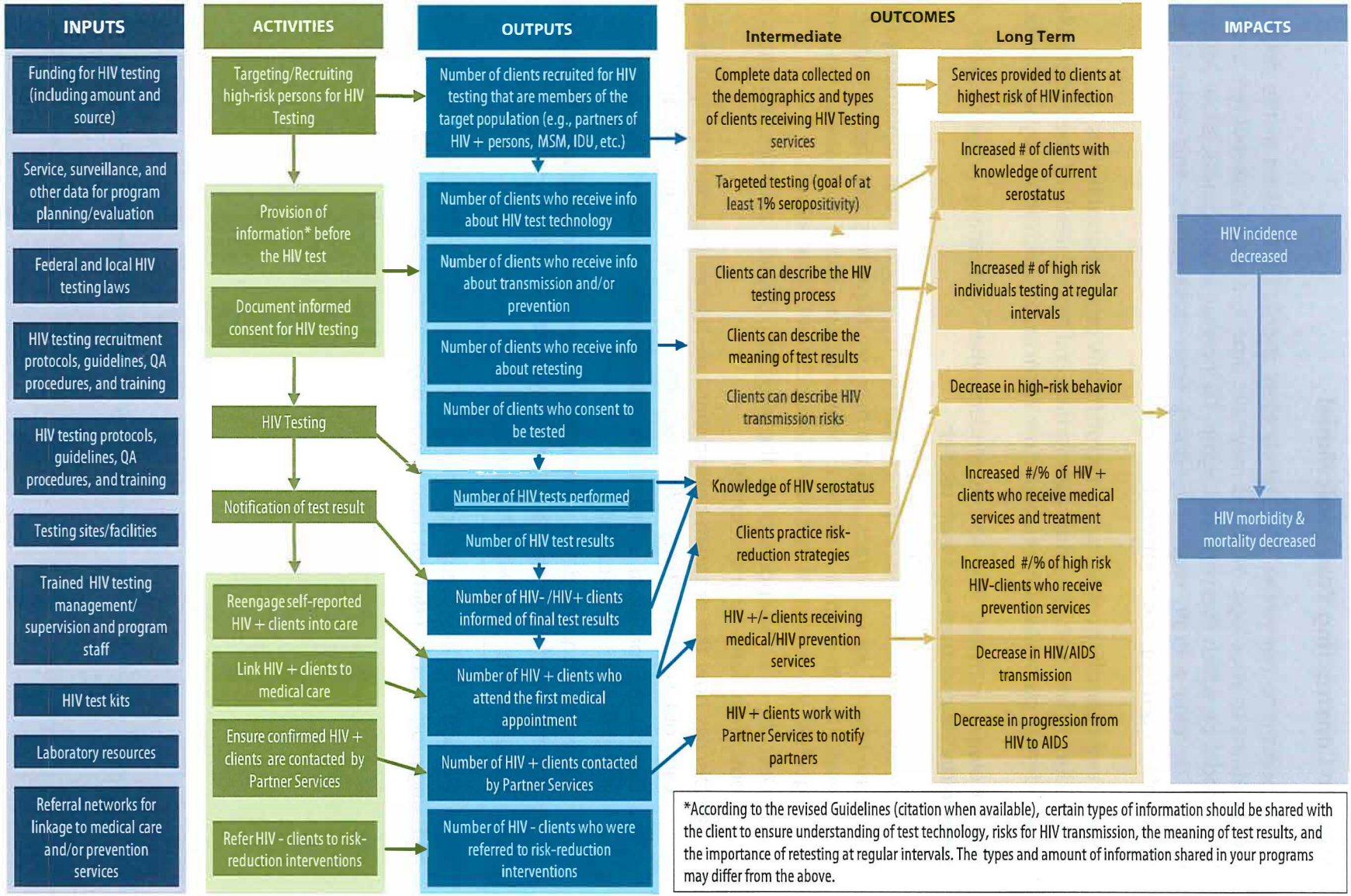
5.	**<u>Outreach, Testing, and Linkage (OTL) with PrEP Navigation</u>** OTL includes targeted outreach that includes HIV testing and linkage to other services, such as PrEP navigation. PrEP Navigation is a process of service delivery to help a person obtain timely, essential and appropriate PrEP-related medical and social services to optimize his or her health and prevent HIV transmission and acquisition. In addition, targeted condom distribution to people living with HIV/AIDS and individuals at high risk of contracting HIV is provided. **Funded Contractors:** • AIDS CT, Hartford, CT (860) 247-2437 • APEX, Danbury, CT (203) 778-2437 • A Place to Nourish your Health (APNH), New Haven, CT (203) 624-0947 • Family Centers, Stamford, CT (203) 977-5096 • GBAPP, Inc., Bridgeport, CT (203) 366-8255 • Hartford Gay and Lesbian Health Collective, Hartford, CT (860) 278-4163 • Perceptions Programs, Willimantic, CT (860) 450-7128 • Waterbury Health Department, Waterbury, CT (203) 574-6780
6.	**<u>SISTA</u>** SISTA (Sisters Informing Sisters about Topics on AIDS) is a peer-led, skill-building intervention project to prevent HIV infection in African American women. It is delivered in 5 sessions and includes discussions of self-esteem, relationships, and sexual health. **Funded Contractors:** • InterCommunity, Inc., East Hartford, CT (860) 461-0130
7.	**<u>Drug User Health Programs</u>** Drug User Health (Includes three components; Syringe Services Program, Overdose Prevention, and Harm Reduction Education). Drug User Health services are a scope of services that underlines a harm reduction philosophy that emphasizes “meeting drug users where they are” by providing services that reduce blood-borne infections (e.g., HIV/HCV), and support harm reduction activities that addresses drug users’ structural and social barriers to care and treatment. **Funded Contractors:** • AIDS CT, Hartford, CT (860) 247-2437 • Alliance for Living, New London, CT (860) 447-0884 x231 • APEX, Danbury, CT (203) 778-2437 • Family Centers, Stamford, CT (203) 977-5096 • GBAPP, Inc., Bridgeport, CT (203) 366-8255 • Greater Hartford Harm Reduction Coalition, Hartford, CT (860) 263-4146 • Perceptions Programs, Willimantic, CT (860) 450-7128 • Waterbury Health Department, Waterbury, CT (203) 574-6780 • Yale University Community HC Van, New Haven, CT (203) 737-4047

Flow-Chart: OTL HIV Testing Algorithm



HIV Testing and Linkage to Care in Non-Clinical Settings Logic Model

Problem Statement: An estimated 56,300 new HIV infections occur in the United States, each year. Available evidence suggests that the majority of new infections are caused by persons unaware of their HIV infection, and an estimated one-quarter of those who are infected with HIV do not know they are infected. CDC's Revised Guidelines for HIV Testing in Nonclinical Settings emphasize targeting high risk populations, utilizing testing algorithms, and linking HIV-positive and HIV-negative persons to medical care and/or prevention interventions.



*According to the revised Guidelines (citation when available), certain types of information should be shared with the client to ensure understanding of test technology, risks for HIV transmission, the meaning of test results, and the importance of retesting at regular intervals. The types and amount of information shared in your programs may differ from the above.

Steps to Constructing Your Logic Model

It is important to remember that stakeholders should be involved in the development or modifications to your logic model. It may take time to engage stakeholders and construct a logic model on which everyone can agree. To increase effectiveness, allow yourself enough time to develop a draft, request feedback from stakeholders, and revise it accordingly. Stakeholders can help you do the following:

- Target specific populations or recruit for HIV prevention activities
- Identify and describe priority prevention and service needs of specific populations
- Identify particular services or partner agencies to which you link your clients

The following activities are recommended when convening program staff and other stakeholders in constructing a logic model:

1. Revisit the problem your non-clinical HIV TLC program was implemented to address, the goal of your program, and the program objectives (see the section on formative evaluation in chapter 2 of the Implementation Guide for assistance in identifying the goals of your program and the various program components).
2. Describe the components of the program (inputs, activities, outputs, short-term outcomes, long-term outcomes).
3. Discuss how the program components are related (e.g., Which input is necessary to carry out a certain activity? Which activities and outputs correspond?).
4. Depict the program component relationships identified by program staff and stakeholders in a logic model.
5. Review the logic model to make sure it depicts the understanding of the program. Ask stakeholders for feedback and make any needed revisions.
6. Share the final copy with all stakeholders.

In the text box to follow, Jacob Dougherty of Diverse and Resilient, Inc. discusses the value of revisiting programs that did not have SMART objectives or logic models.

Implementing HIV Testing in Nonclinical Settings: Frequently Asked Questions

1. **I'm not sure if my agency is a clinical setting or a nonclinical setting. Based on the definition in this Implementation Guide, how do I decide which strategy my agency should follow?**
   The distinction between clinical and nonclinical HIV testing settings is sometimes blurred because many agencies are beginning to offer clinical services within nonclinical settings. If your agency is located within the community—either at a fixed venue or mobile/outreach site, conducts recruitment services to get high-risk populations in for targeted HIV testing, and is accessed specifically for HIV testing by persons who might not access other medical services regularly—you may be considered a nonclinical testing setting.

2. **Which targeting and recruitment strategy will be most effective for helping my agency meet our objective of testing previously undiagnosed HIV-positive persons?**
   It is not easy to say what strategy is most effective for recruiting previously undiagnosed HIV-positive persons. Agencies should be familiar with the high-risk populations in their area (i.e., their focus population), and then design a strategy that takes into consideration: 1) who is their focus population; 2) where is the best place to locate them; 3) when is the best time to reach them; 4) what messages should be delivered; 5) how these messages should be delivered; and 6) who should deliver these messages. Studies have shown that social networking strategy can be very effective for recruiting high-risk persons for HIV testing, but it must be done well in order to be successful. There is increasing evidence about the use of social media, including social networking apps, for recruiting high-risk HIV testing clients. Sometimes the most effective way is through internal referrals from other services offered at an agency, such as needle exchange or substance abuse treatment services. Social marketing (i.e., posters, billboards, advertisements on public transportation) can be helpful for creating general awareness, but may need to be tailored in order to reach the highest-risk clients. It may be helpful to use a combination of multiple recruitment strategies at the same time. Agencies should look at their HIV testing data on a regular basis and make changes to their recruitment strategy if they are not meeting their objective of testing previously undiagnosed HIV-positive persons.

3. **How often should people get tested for HIV, especially key populations such as men who have sex with men (MSM) and people who inject drugs (PWID)?**
   CDC recommends that clinicians and providers test everyone between the ages of 13 and 64 at least once as part of routine healthcare, and test persons who engage in behaviors that put them at high risk for HIV infection—such as sexually active MSM, PWID and their sex partners, or persons who exchange sex for money or drugs—at least once a year. Additionally, for sexually active MSM, providers should consider the benefits of more frequent screening (e.g., 3-6 months).

4. **Why is the laboratory-based HIV testing algorithm recommended for nonclinical settings? Isn't it easier for nonclinical settings to just do onsite rapid HIV testing?**
   The CDC-recommended laboratory-based HIV testing algorithm can identify HIV infections earlier than point-of-care rapid tests that use whole blood specimens, which are often used in nonclinical settings. If a nonclinical testing site has the option of performing laboratory-based testing following this algorithm—including the capacity for venipuncture sample collection—then they may choose this algorithm because it allows them to detect HIV as early as possible after a client's exposure. It may be particularly important for clients with a considerable risk of acute HIV infection. However, rapid HIV antibody tests can be attractive for use in settings that may not be equipped to conduct venipuncture, and clients can get the results from their screening test quickly. Agencies should also consider other factors, such as feasibility of implementation, likelihood of being able to follow-up with the client, and cost.

5. **With all the advances in new HIV testing technologies in recent years, why does CDC still recommend a window period of 3 months?**
   The window period refers to the time from when a client is exposed to HIV to when an HIV test can detect infection. The initial portion of the window period (the eclipse period) may last from a few days to several weeks. During this time the virus replicates near the site of infection but is not yet detectable in the blood by any HIV test, which makes it hard to know how long this period is. Additionally, current estimates for the window period time frame are based on plasma specimens, and plasma is not used for HIV testing in nonclinical settings. These estimates are currently under review. Estimates of the window period for tests conducted with blood or oral fluid do not currently exist, but a study is under way to quantify the delay in detection in blood and oral fluid rapid tests, compared to tests conducted on plasma. When data from these studies become available, window period estimates will be updated accordingly.

6. **The Implementation Guide states that the evidence is inconclusive about the ability of combination antigen/antibody rapid tests (4th generation rapid tests) to accurately detect the p24 antigen in whole blood specimens. CDC has not provided recommendations about the use of these tests, but some agencies have started to use them. Why has CDC not provided recommendations about the use of these tests?**
   CDC has not provided definitive guidance on the use of combination antigen/antibody rapid tests because we are still gathering data on their performance. For HIV testing done on plasma specimens in laboratory settings, it appears as though the combination antigen/antibody rapid tests do not perform as well as other tests currently recommended in CDC's laboratory testing guidelines, but do perform better than tests that detect antibody alone, which are no longer recommended for use in laboratory settings. The laboratory HIV testing guidance can be accessed at http://www.cdc.gov/hiv/testing/laboratorytests.html. However, for HIV testing done on whole blood specimens in nonclinical settings, combination antigen/antibody rapid tests may perform as well or better than other rapid tests. The results of these assessments will be presented as they are finalized, and guidelines and recommendations will be updated, as appropriate.

7. **Oral fluid antibody tests have been shown to detect infection a month or more later than blood-based tests because there is a lower concentration of HIV antibodies in oral fluid than in blood. Should my agency stop performing oral fluid testing?**

Using a laboratory test, oral fluid was shown to detect infection a month later than blood. CDC is conducting a study to quantify the delay in detection in oral fluid rapid tests relative to blood tests. Oral fluid tests adequately detect established infections, but should not be used if early infection is a possibility. If they are used when early infection is possible and the result is negative, a retest should be conducted using a more sensitive test. In addition, there is evidence that oral fluid tests do not sufficiently detect infection when persons are taking pre-exposure prophylaxis. While oral fluid is not ideal for identifying early HIV infection, including infections occurring while taking pre-exposure prophylaxis, it may be appealing in outreach or mobile settings because collecting oral fluid does not involve a fingerstick or venipuncture to perform the test. If there are options, agencies should choose an algorithm that allows them to detect HIV as early as possible after exposure. Agencies should also consider other factors, such as feasibility of implementation, likelihood of being able to follow-up with the client, and cost.

8. **How should HIV testing providers report a preliminary HIV-positive test result if they are not doing onsite confirmation?**
   CDC recommends reporting of all HIV-related laboratory test results; however, jurisdictions have the regulatory authority and confidentiality protections to collect information on persons with diagnosed HIV infection and these vary across states. Nonclinical HIV testing providers should refer to local/state HIV reporting law/regulations for specific guidance for HIV reporting. The supplemental or confirmatory test may be done onsite. If supplemental or confirmatory test is not done onsite but instead either the client or their specimen is sent to another healthcare provider or laboratory for supplemental testing, then the result of the preliminary test should also be sent to that healthcare provider or laboratory (where sharing the result with a party other than the health department is not restricted by law). This is so that whoever runs the supplemental test can report both results to the health department, so that both results can be linked to the patient more easily. If the supplemental or confirmatory test is not done onsite and healthcare provider or laboratory reports the result of the supplemental test back to the original testing site that did the preliminary test, then that site should report both results to the health department if they have not already been reported. In the rare case that a supplemental test is not performed, or the original testing site does not receive results of the supplemental test, it may still be worthwhile to report the preliminary result to the health department in the event that they have the ability to track down the patient or link the result of the supplemental test to the patient.

9. **Should agencies integrate HIV testing with STI testing and other tests such as hepatitis C virus (HCV)?**
   Many nonclinical HIV testing sites are starting to offer other services in addition to only HIV testing. Due to high rates of co-infection it may be important to offer diagnostic services for other sexually transmitted infections (STIs) and HCV. Where funding and resources allow, HIV testing sites are encouraged to integrate other diagnostic services such as STI and HCV testing.

10. **What is the role of nonclinical HIV testing sites in supporting home-based HIV testing? How can agencies support clients who use home HIV tests and/or offer home-based HIV testing kits?**
    Some HIV testing providers in nonclinical settings have supported home-based HIV testing by strengthening relationships with shops and pharmacies where these test kits are sold, so that shopkeepers and pharmacists can refer clients to them with questions or for follow-up. Some

agencies have developed palm cards or other informational inserts with their contact information that can be distributed with the test kits (if the store agrees). Some agencies—through an agreement with the test kit companies—have also distributed the kits for clients and their partners to use at home on their own. The agency then serves as a resource for follow-up and referrals once the client(s) know their HIV status. These are just a few examples of how nonclinical HIV testing providers are currently supporting home-based testing, and more opportunities are being explored.

11. CDC recommends that HIV testing sessions in nonclinical settings be brief, information-based, and tailored to clients' needs. Why is extensive pretest and posttest prevention counseling no longer part of the HIV testing event?

Based on emerging evidence suggesting the limited benefit of HIV prevention counseling, best practices in the field for making HIV testing as easy and accessible as possible, and the reality that many people accessing HIV testing have already been tested and received HIV prevention counseling before, the HIV testing protocol recommended in this Implementation Guide no longer includes extensive pre- and posttest counseling. Clients who need HIV prevention counseling may still receive it through one of CDC's evidence-based interventions (EBIs) or as a separate service. HIV testing providers should still have strong communication skills and be prepared to help clients address the various issues that may arise during an HIV testing session, but in general the emphasis is on making HIV testing service delivery as smooth and seamless as possible and empowering clients to access appropriate follow-up services based on their HIV test results and their specific needs.

12. Since extensive pretest and posttest prevention counseling is removed from the HIV testing event, how can HIV testing providers make sure that clients are still getting the services they need, such as mental health services, substance abuse treatment, housing, etc.?

Despite the separation of HIV prevention counseling from the HIV testing event, HIV testing services should still be client-centered, and HIV testing providers should have strong communication skills that prepare them to help clients address the various issues that may arise during an HIV testing session. Different clients will have different needs, and every effort should still be made to link clients with services that address their HIV-related health and wellness needs. Testing providers are encouraged to establish strong relationships with agencies that provide medical care, social and behavioral services in order to provide referrals to meet client's needs.

13. How much flexibility do agencies, including Health Departments, have in adapting this guidance to develop their own HIV testing protocols for nonclinical settings that are even more streamlined?

Some HIV testing agencies have already been moving toward a more streamlined approach to HIV testing with less emphasis on counseling. HIV testing agencies and health departments are encouraged to follow the general structure presented for an HIV testing session in this Implementation Guide, and to continue identifying ways of making HIV testing service delivery as smooth and seamless as possible. Protocols can be streamlined even more than what is presented in the Implementation Guide, but should allow for some flexibility with clients who need a bit more attention in order to access appropriate follow-up services based on their HIV test results and their situations.

14. Why isn't there more emphasis on pre-exposure prophylaxis (PrEP) and nonoccupational postexposure prophylaxis (nPEP) and screening HIV-negative clients for PrEP as part of the HIV testing session?

Nonclinical providers ARE encouraged to emphasize risk reduction strategies that will help the client remain HIV-negative, including nPEP and PrEP. Clients receiving an HIV-negative test result should receive information about the availability and benefits of PrEP and should be referred to a PrEP or nPEP counselor or medical provider if they are at substantial risk for acquiring HIV, as outlined in step 5 of the HIV testing protocol for individuals, "Develop a Care, Treatment, and Prevention Plan Based on Results."

PrEP guidelines and additional resources can be accessed at http://www.cdc.gov/hiv/risk/prep/index.html and nPEP guidelines can be accessed at http://www.cdc.gov/hiv/risk/pep/index.html.

15. CDC recommends couples or partner HIV testing, but doesn't this violate HIPAA regulations?

Couples or partner HIV testing does not violate HIPAA regulations. As long as both partners give their informed consent, then they may be tested together and receive their results together.

16. My agency's leadership is afraid that couples or partner HIV testing will lead to violence in the relationship, especially if the couple's test results are different. What information exists about the possibility of violence following couples or partner testing?

There is no evidence that couples or partner testing leads to increased violence in a relationship. However, intimate partner violence is a concern for both individuals and couples who test for HIV, and HIV testing providers should know what resources exist in their communities to help address clients facing intimate partner violence, and should build relationships with these services. This is discussed in more detail in the training for couples HIV testing and counseling, or Testing Together. Information about training for Testing Together can be accessed at http://effectiveinterventions.cdc.gov.

17. Why has the recently updated National HIV/AIDS Strategy changed the time for linking people living with HIV to care and treatment from 90 days to 30 days?

Earlier access to HIV care and treatment can help HIV-positive clients stay healthy and prevent transmission to HIV-negative partners.

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Keeping Records

Employee Training Records

- Employers are required to keep safety training records for at least three years.
- Employees should know where their records are located and who is responsible for maintain the training records.
- The training records must include:
    - Your job title (at the time of training).
    - Dates of your training sessions.
    - Contents or summary of your training sessions.
    - Names and qualifications of persons conducting you training.
- According to the OSHA Bloodborne Pathogens Standard, you can request your training record at any time, and your employer must provide the records to you or your authorized representative within 15 working days of the request.

Medical Records

According to OSHA regulation, “Access to Employee Exposure and Medical Records” your medical records must be kept confidential and retained for the duration of your employment plus 30 years. These records must include all of your occupational exposure reports, all medical follow-up documents, and written medical opinions related to any occupational exposures.

- Employee medical records must be provided within 15 working days of your written request.
- Your employer must provide you with the name and address of the responsible person or department to whom the request should be made.

OSHA Recordkeeping

Every exposure incident report must be evaluated by a trained professional (identified in your organization’s Exposure Control Plan) to determine if the exposure incident records meet OSHA’s recordkeeping requirements.

Checklist for Referral to Partner Services for Persons Newly Diagnosed With HIV in Connecticut

Please use the checklist below to ensure that you have provided all of the information needed for a timely referral to Partner Services:

☐	Inform the client that the State Health Department will be contacting them to provide information on supportive resources and assist with confidential notification of partners.
☐	Complete the *Client Referral Form.* • The DIS assigned to interview the client will be contacting the treating clinician's office to obtain additional information as needed. If you are able to provide a direct extension and name of the best contact in the clinician's office, it would be greatly appreciated.
☐	Did the client discuss partners with you? If so, complete the *Partner Referral Form* for each partner.

☐	Call and speak with the Regional DIS Supervisor to alert DPH that a referral is incoming. Region is determined by the town in which the client lives.
	• Region 1 – Counties: Hartford, Litchfield, Tolland, Windham, New London, and interior of Middlesex
	  ○ Ava Nepaul, DIS Supervisor - (860) 509-8239
	• Region 2 – Fairfield, New Haven, and shoreline of Middlesex
	  ○ Wanda Richardson, DIS Supervisor - (203) 946-7233

☐	Fax referral forms and lab results to the DIS Supervisor. • Labs must include the confirmatory HIV test information. • Additional tests for which information is requested are: syphilis, chlamydia, and gonorrhea.* • If you have results of Hep C and tuberculosis (QTF) tests, please send that information as well.* • **If the asterisked (*) information is not available, do not delay calling the DIS Supervisor to report and submit the *Client Referral Form* and HIV labs.** It is pretty typical that the post-diagnosis screening test results will roll in later.

Social Networking Strategies
Quality Assurance Guidance

Quality Assurance Activities
Contractor shall conduct the following quality assurance activities:

- Follow the DSHS approved SNS implementation plan. The implementation plan will be approved by DSHS and provided to the contractor by the start date of the contract.

- Ensure SNS staff implements each of the following activities:

  Phase I: Recruiter Enlistment (identify, screen, and invite potential recruiters to participate in program); *during the pilot program it is recommended that the initial recruiter be an HIV positive member of your target population(s)*

  While the CDC curriculum states that the initial recruiter for each network must be HIV+ the 2010 DSHS performance measures indicate that only 1 recruiter must be HIV+. This is acceptable during the first year of the pilot. However, DSHS highly encourages the use of multiple HIV+ recruiters throughout the program.

  Documentation: Enlistment/Screening Checklist
  Contractors can develop their own forms or use those provided by CDC (see talking points document HO#12 in the SNS training manual and page 7 of the SNS data collection forms

  Phase II: Recruiter Engagement (orient and interview recruiters about network associates; coach recruiters on how to approach network associates)

  Documentation:
  Orientation - develop form that covers components listed on p.3 under day 2 of training manual

  Interview - Contractors can develop their own forms or use those provided by CDC (see session components in HO #15 in the SNS training manual and forms for SNS data collection

Coaching - develop coaching checklist similar to HO #18 in the SNS training manual

Phase III: Recruitment of Network Associates (recruiters recruit network associates for counseling and testing);

Documentation: Contractors can develop their own SNS forms. If you require assistance, please refer to your DPH Contract Manager.

Phase IV: Outreach, Testing, and Linkage to Care (provide HIV testing and minimal counseling to network associates and link clients who test positive into care and preventive services)

Documentation: At minimum, contractors must track SNS OTL activity in RECN or the Testing w/o Counseling data bases. Programs are encouraged to develop additional forms to monitor network associates that receive CTR services weekly/monthly and that clearly link network associates to their recruiter.

Frequency of Monitoring Activities
SNS program staff should be monitored per the guidance below:

Length of time staff have been performing the intervention	Frequency
0-6 months	Twice a month
7-12 months	Monthly
1-2 years	Quarterly
2 years or more	Every 6 months

Monitoring should at minimum include observation of any of the following activities:

- Recruiter Enlistment
- Orientation
- Interviewing
- Coaching
- Testing (if the SNS coordinator will be conducting tests)
- Recruiter file reviews

- First 6 months: 20% of charts monthly, OR 4/ month, whichever is greater;

- Over 6 months and thereafter: 20% of charts quarterly, OR 4/ quarter, whichever is greater

Files should include the following information/forms:

- orientation form
- screening form (demographics, risk factors, HIV status, etc.) DSHS will not require proof of status as a condition for participation
- consent/confidentiality form
- recruiter information (locating info., test history, risk group, network associates identified and referred to CTR, etc.)
- interview form
- coaching form
- tangible reinforcements received
- additional notes (if needed)

Incentives

Funds may be used to purchase tangible reinforcements (bus tokens, movie gift cards, food gift cards, t-shirts, grocery store gift cards, etc.) to encourage at risk clients to participate in prevention programs. *Tangible reinforcements must be approved in advance by DSHS Program. Contractor shall maintain a policy regarding the use of tangible reinforcements and a log for tracking the distribution of tangible reinforcements. The policy and log are subject to review by DSHS Program during program reviews and at any other time.* The policy must limit the use of tangible reinforcements to the following types of situations: for recruitment of clients into PBC, SNS, CRCS, and EBIs, for retention of clients in EBIs, for clients upon completion of all sessions of an EBI, for recruitment and retention of peer volunteers, for clients who return for HIV testing and to encourage clients to return for test results. Funds may not be used to make cash payments or cash-equivalent payments to intended recipients of services except as noted above.

Agencies must have an incentive log that keeps track of incentives on hand (available inventory), documents when the incentives were purchased, what the incentives are, the distribution of the items and the remaining balance.

<u>Things to consider:</u>

- Will you offer extra incentives if NA is escorted by recruiter vs. walking into testing venue alone?

- How will you handle incentives for recruiters that have conversations with associates but no one comes in to test?
- Alternative incentives: condom store, thumb drives, etc.

Data Reporting

The SNS is an effective HIV Prevention Outreach Strategy and should be recorded in your agency's Tri–Annual report under the outreach section.

Patient Identification (record all dates as mm/dd/yyyy)

*First Name	*Middle Name	*Last Name	Last Name Soundex
Alternate Name Type (ex: Alias, Married)	*First Name	*Middle Name	*Last Name
Address Type ☐ Residential ☐ Bad address ☐ Correctional facility ☐ Foster home ☐ Homeless ☐ Postal ☐ Shelter ☐ Temporary	*Current Address, Street		Address Date __ __ /__ __ /__ __ __ __
*Phone ( )	City	County	State/Country	*ZIP Code
*Medical Record Number	*Other ID Type	*Number	

U.S. Department of Health and Human Services

Adult HIV Confidential Case Report Form

(Patients ≥13 years of age at time of diagnosis) *Information NOT transmitted to CDC

Centers for Disease Control and Prevention (CDC)

Health Department Use Only (record all dates as mm/dd/yyyy)

Form approved OMB no. 0920-0573 Exp. 06/30/2019

Date Received at Health Department __ __ /__ __ /__ __ __ __	eHARS Document UID	State Number
Reporting Health Dept—City/County	City/County Number	
Document Source	Surveillance Method ☐ Active ☐ Passive ☐ Follow up ☐ Reabstraction ☐ Unknown	
Did this report initiate a new case investigation? ☐ Yes ☐ No ☐ Unknown	Report Medium ☐ 1-Field visit ☐ 2-Mailed ☐ 3-Faxed ☐ 4-Phone ☐ 5-Electronic transfer ☐ 6-CD/disk	

Facility Providing Information (record all dates as mm/dd/yyyy)

Facility Name			*Phone ( )
*Street Address			
City	County	State/Country	*ZIP Code
Facility Type	*Inpatient*: ☐ Hospital ☐ Other, specify _____	*Outpatient*: ☐ Private physician's office ☐ Adult HIV clinic ☐ Other, specify _____	*Screening, Diagnostic, Referral Agency*: ☐ CTS ☐ STD clinic ☐ Other, specify _____	*Other Facility*: ☐ Emergency room ☐ Laboratory ☐ Corrections ☐ Unknown ☐ Other, specify _____
Date Form Completed __ __ /__ __ /__ __ __ __	*Person Completing Form		*Phone ( )

Patient Demographics (record all dates as mm/dd/yyyy)

Sex Assigned at Birth ☐ Male ☐ Female ☐ Unknown	Country of Birth ☐ US ☐ Other/US dependency (please specify) _____	
Date of Birth __ __ /__ __ /__ __ __ __	Alias Date of Birth __ __ /__ __ /__ __ __ __	
Vital Status ☐ 1-Alive ☐ 2-Dead	Date of Death __ __ /__ __ /__ __ __ __	State of Death
Current Gender Identity ☐ Male ☐ Female ☐ Transgender male-to-female (MTF) ☐ Transgender female-to-male (FTM) ☐ Unknown ☐ Additional gender identity (specify) _____		
Ethnicity ☐ Hispanic/Latino ☐ Not Hispanic/Latino ☐ Unknown		Expanded Ethnicity
Race (check all that apply) ☐ American Indian/Alaska Native ☐ Asian ☐ Black/African American ☐ Native Hawaiian/Other Pacific Islander ☐ White ☐ Unknown		Expanded Race

Residence at Diagnosis (add additional addresses in Comments) (record all dates as mm/dd/yyyy)

Address Type (check all that apply to address below) ☐ Residence at HIV diagnosis ☐ Residence at stage 3 (AIDS) diagnosis ☐ Check if SAME as current address			
*Street Address			
City	County	State/Country	*ZIP Code

Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0920-0573). **Do not send the completed form to this address.**

STATE/LOCAL USE ONLY	
*Provider Name (Last, First, M.I.)	*Phone ( )
Hospital/Facility	

Facility of Diagnosis (add additional facilities in Comments)

Diagnosis Type (check all that apply to facility below) ☐ HIV ☐ Stage 3 (AIDS) ☐ Check if SAME as facility providing information			
Facility Name			***Phone** ( )
***Street Address**			
City	**County**	**State/Country**	***ZIP Code**
Facility Type *Inpatient*: ☐ Hospital ☐ Other, specify _____	*Outpatient*: ☐ Private physician's office ☐ Adult HIV clinic ☐ Other, specify _____	*Screening, Diagnostic, Referral Agency*: ☐ CTS ☐ STD clinic ☐ Other, specify _____	*Other Facility*: ☐ Emergency room ☐ Laboratory ☐ Corrections ☐ Unknown ☐ Other, specify _____
***Provider Name**	***Provider Phone** ( )		**Specialty**

Patient History (respond to all questions) (record all dates as mm/dd/yyyy) ☐ Pediatric Risk (please enter in Comments)

After 1977 and before the earliest known diagnosis of HIV infection, this patient had:	
Sex with male	☐ Yes ☐ No ☐ Unknown
Sex with female	☐ Yes ☐ No ☐ Unknown
Injected nonprescription drugs	☐ Yes ☐ No ☐ Unknown
Received clotting factor for hemophilia/coagulation disorder Specify clotting factor: Date received __ __/__ __/__ __ __ __	☐ Yes ☐ No ☐ Unknown
HETEROSEXUAL relations with any of the following:	
HETEROSEXUAL contact with intravenous/injection drug user	☐ Yes ☐ No ☐ Unknown
HETEROSEXUAL contact with bisexual male	☐ Yes ☐ No ☐ Unknown
HETEROSEXUAL contact with person with hemophilia/coagulation disorder with documented HIV infection	☐ Yes ☐ No ☐ Unknown
HETEROSEXUAL contact with transfusion recipient with documented HIV infection	☐ Yes ☐ No ☐ Unknown
HETEROSEXUAL contact with transplant recipient with documented HIV infection	☐ Yes ☐ No ☐ Unknown
HETEROSEXUAL contact with person with documented HIV infection, risk not specified	☐ Yes ☐ No ☐ Unknown
Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments)	☐ Yes ☐ No ☐ Unknown
First date received __ __/__ __/__ __ __ __ Last date received __ __/__ __/__ __ __ __	
Received transplant of tissue/organs or artificial insemination	☐ Yes ☐ No ☐ Unknown
Worked in a healthcare or clinical laboratory setting	☐ Yes ☐ No ☐ Unknown
If occupational exposure is being investigated or considered as primary mode of exposure, specify occupation and setting:	
Other documented risk (please include detail in Comments)	☐ Yes ☐ No ☐ Unknown

Clinical: Acute HIV Infection and Opportunistic Illnesses (record all dates as mm/dd/yyyy)

Suspect acute HIV infection? *If YES, complete the two items below; enter documented negative HIV test data in Laboratory Data section, and enter patient or provider report of previous negative HIV test in HIV Testing History section.*	☐ Yes ☐ No ☐ Unknown
Clinical signs/symptoms consistent with acute retroviral syndrome (e.g., fever, malaise/fatigue, myalgia, pharyngitis, rash, lymphadenopathy)? Date of sign/symptom onset __ __/__ __/__ __ __ __	☐ Yes ☐ No ☐ Unknown
Other evidence suggestive of acute HIV infection? *If YES, please describe:* Date of evidence __ __/__ __/__ __ __ __	☐ Yes ☐ No ☐ Unknown

Opportunistic Illnesses

Diagnosis	Dx Date	Diagnosis	Dx Date	Diagnosis	Dx Date
Candidiasis, bronchi, trachea, or lungs		Herpes simplex: chronic ulcers (>1 mo. duration), bronchitis, pneumonitis, or esophagitis		M. tuberculosis, pulmonary[1]	
Candidiasis, esophageal		Histoplasmosis, disseminated or extrapulmonary		M. tuberculosis, disseminated or extrapulmonary[1]	
Carcinoma, invasive cervical		Isosporiasis, chronic intestinal (>1 mo. duration)		Mycobacterium, of other/unidentified species, disseminated or extrapulmonary	
Coccidioidomycosis, disseminated or extrapulmonary		Kaposi's sarcoma		Pneumocystis pneumonia	
Cryptococcosis, extrapulmonary		Lymphoma, Burkitt's (or equivalent)		Pneumonia, recurrent, in 12 mo. period	
Cryptosporidiosis, chronic intestinal (>1 mo. duration)		Lymphoma, immunoblastic (or equivalent)		Progressive multifocal leukoencephalopathy	
Cytomegalovirus disease (other than in liver, spleen, or nodes)		Lymphoma, primary in brain		Salmonella septicemia, recurrent	
Cytomegalovirus retinitis (with loss of vision)		Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary		Toxoplasmosis of brain, onset at >1 mo. of age	
HIV encephalopathy				Wasting syndrome due to HIV	

[1]If a diagnosis date is entered for either tuberculosis diagnosis above, provide RVCT Case Number:

Laboratory Data (record additional tests and tests not specified below in Comments) (record all dates as mm/dd/yyyy)

HIV Immunoassays (Nondifferentiating)

TEST 1 ☐ HIV-1 IA ☐ HIV-1/2 IA ☐ HIV-1/2 Ag/Ab ☐ HIV-1 WB ☐ HIV-1 IFA ☐ HIV-2 IA ☐ HIV-2 WB
Test brand name/Manufacturer _____ **Lab name** _____
Facility name _____ **Provider name** _____
Result ☐ Positive ☐ Negative ☐ Indeterminate **Collection Date** __ __ /__ __ /__ __ __ __ ☐ **Point-of-care rapid test**

TEST 2 ☐ HIV-1 IA ☐ HIV-1/2 IA ☐ HIV-1/2 Ag/Ab ☐ HIV-1 WB ☐ HIV-1 IFA ☐ HIV-2 IA ☐ HIV-2 WB
Test brand name/Manufacturer _____ **Lab name** _____
Facility name _____ **Provider name** _____
Result ☐ Positive ☐ Negative ☐ Indeterminate **Collection Date** __ __ /__ __ /__ __ __ __ ☐ **Point-of-care rapid test**

HIV Immunoassays (Differentiating)

☐ **HIV-1/2 type-differentiating immunoassay** (differentiates between HIV-1 Ab and HIV-2 Ab)
Role of test in diagnostic algorithm ☐ Screening/initial test ☐ Confirmatory/supplemental test
Test brand name/Manufacturer _____ **Lab name** _____
Facility name _____ **Provider name** _____
Result[1] ***Overall interpretation***: ☐ HIV-1 positive ☐ HIV-2 positive ☐ HIV positive, untypable ☐ HIV-2 positive with HIV-1 cross-reactivity ☐ HIV-1 indeterminate ☐ HIV-2 indeterminate ☐ HIV indeterminate ☐ HIV negative
Analyte results: HIV-1 Ab: ☐ Positive ☐ Negative ☐ Indeterminate **Collection Date** __ __ /__ __ /__ __ __ __ ☐ **Point-of-care rapid test**
HIV-2 Ab: ☐ Positive ☐ Negative ☐ Indeterminate
[1]Always complete the overall interpretation. Complete the analyte results when available.

☐ **HIV-1/2 Ag/Ab differentiating immunoassay** (differentiates between HIV Ag and HIV Ab)
Test brand name/Manufacturer _____ **Lab name** _____
Facility name _____ **Provider name** _____
Result ☐ Ag positive ☐ Ab positive ☐ Both (Ag and Ab positive) ☐ Negative ☐ Invalid
Collection Date __ __ /__ __ /__ __ __ __ ☐ **Point-of-care rapid test**

☐ **HIV-1/2 Ag/Ab and type-differentiating immunoassay** (differentiates among HIV-1 Ag, HIV-1 Ab, and HIV-2 Ab)
Test brand name/Manufacturer _____ **Lab name** _____
Facility name _____ **Provider name** _____
Result[2] ***Overall interpretation***: ☐ Reactive ☐ Nonreactive ☐ **Index value** _____
Analyte results: HIV-1 Ag: ☐ Reactive ☐ Nonreactive ☐ Not reportable due to high Ab level **Index value** _____
HIV-1 Ab: ☐ Reactive ☐ Nonreactive ☐ Reactive undifferentiated **Index value** _____
HIV-2 Ab: ☐ Reactive ☐ Nonreactive ☐ Reactive undifferentiated **Index value** _____
Collection Date __ __ /__ __ /__ __ __ __ ☐ **Point-of-care rapid test**
[2]Complete the overall interpretation and the analyte results.

HIV Detection Tests (Qualitative)

TEST ☐ HIV-1 RNA/DNA NAAT (Qualitative) ☐ HIV-1 culture ☐ HIV-2 RNA/DNA NAAT (Qualitative) ☐ HIV-2 culture
Test brand name/Manufacturer _____ **Lab name** _____
Facility name _____ **Provider name** _____
Result ☐ Positive ☐ Negative ☐ Indeterminate **Collection Date** __ __ /__ __ /__ __ __ __

HIV Detection Tests (Quantitative viral load) Note: Include earliest test at or after diagnosis.

TEST 1 ☐ HIV-1 RNA/DNA NAAT (Quantitative viral load) ☐ HIV-2 RNA/DNA NAAT (Quantitative viral load)
Test brand name/Manufacturer _____ **Lab name** _____
Facility name _____ **Provider name** _____
Result ☐ Detectable ☐ Undetectable **Copies/mL** _____ **Log** _____ **Collection Date** __ __ /__ __ /__ __ __ __

TEST 2 ☐ HIV-1 RNA/DNA NAAT (Quantitative viral load) ☐ HIV-2 RNA/DNA NAAT (Quantitative viral load)
Test brand name/Manufacturer _____ **Lab name** _____
Facility name _____ **Provider name** _____
Result ☐ Detectable ☐ Undetectable **Copies/mL** _____ **Log** _____ **Collection Date** __ __ /__ __ /__ __ __ __

Drug Resistance Tests (Genotypic)

TEST ☐ HIV-1 Genotype (Unspecified) **Test brand name/Manufacturer** _____
Lab name _____ **Facility name** _____
Provider name _____ **Collection Date** __ __ /__ __ /__ __ __ __

Immunologic Tests (CD4 count and percentage)

CD4 at or closest to diagnosis: CD4 count _____ cells/μL **CD4 percentage** _____ % **Collection Date** __ __ /__ __ /__ __ __ __
Test brand name/Manufacturer _____ **Lab name** _____
Facility name _____ **Provider name** _____

First CD4 result <200 cells/μL or <14%: CD4 count _____ cells/μL **CD4 percentage** _____ % **Collection Date** __ __ /__ __ /__ __ __ __
Test brand name/Manufacturer _____ **Lab name** _____
Facility name _____ **Provider name** _____

Other CD4 result: CD4 count _____ cells/μL **CD4 percentage** _____ % **Collection Date** __ __ /__ __ /__ __ __ __
Test brand name/Manufacturer _____ **Lab name** _____
Facility name _____ **Provider name** _____

Documentation of Tests

Did documented laboratory test results meet approved HIV diagnostic algorithm criteria? ☐ Yes ☐ No ☐ Unknown
If YES, provide specimen collection date of earliest positive test for this algorithm __ __ /__ __ /__ __ __ __
Complete the above only if none of the following was positive: HIV-1 Western blot, IFA, culture, viral load, or qualitative NAAT [RNA or DNA]

If HIV laboratory tests were not documented, is HIV diagnosis documented by a physician? ☐ Yes ☐ No ☐ Unknown
If YES, provide date of diagnosis __ __ /__ __ /__ __ __ __

Date of last documented negative HIV test (before HIV diagnosis date) __ __ /__ __ /__ __ __ __
Specify type of test:

Treatment/Services Referrals (record all dates as mm/dd/yyyy)

Has this patient been informed of his/her HIV infection? ☐ Yes ☐ No ☐ Unknown

This patient's partners will be notified about their HIV exposure and counseled by ☐ 1-Health dept ☐ 2-Physician/Provider ☐ 3-Patient ☐ 9-Unknown

Evidence of receipt of HIV medical care other than laboratory test result (select one; record additional evidence in Comments)
☐ 1-Yes, documented ☐ 2-Yes, client self-report, only Date of medical visit or prescription __ __/__ __/__ __ __ __

For Female Patient

This patient is receiving or has been referred for gynecological or obstetrical services ☐ Yes ☐ No ☐ Unknown

Is this patient currently pregnant? ☐ Yes ☐ No ☐ Unknown

Has this patient delivered live-born infants? ☐ Yes ☐ No ☐ Unknown

For Children of Patient (record most recent birth in these boxes; record additional or multiple births in Comments)

***Child's Name**

Child's Date of Birth __ __/__ __/__ __ __ __

Child's Last Name Soundex

Child's State Number

Facility Name of Birth
(if child was born at home, enter "home birth")

***Phone**
( )

Facility Type
Inpatient: ☐ Hospital ☐ Other, specify_____
Outpatient: ☐ Other, specify _____
Other Facility: ☐ Emergency room ☐ Corrections ☐ Unknown ☐ Other, specify _____

***Street Address**

***ZIP Code**

City

County

State/Country

Antiretroviral Use History (record all dates as mm/dd/yyyy)

Main source of antiretroviral (ARV) use information (select one)
☐ Patient interview ☐ Medical record review ☐ Provider report ☐ NHM&E ☐ Other

Date patient reported information __ __/__ __/__ __ __ __

Ever taken any ARVs? ☐ Yes ☐ No ☐ Unknown

If yes, reason for ARV use (select all that apply)

☐ HIV Tx	ARV medications_____	Date began __ __/__ __/__ __ __ __	Date of last use __ __/__ __/__ __ __ __
☐ PrEP	ARV medications _____	Date began __ __/__ __/__ __ __ __	Date of last use __ __/__ __/__ __ __ __
☐ PEP	ARV medications_____	Date began __ __/__ __/__ __ __ __	Date of last use __ __/__ __/__ __ __ __
☐ PMTCT	ARV medications_____	Date began __ __/__ __/__ __ __ __	Date of last use __ __/__ __/__ __ __ __
☐ HBV Tx	ARV medications_____	Date began __ __/__ __/__ __ __ __	Date of last use __ __/__ __/__ __ __ __
☐ Other (specify reason)_____			
	ARV medications_____	Date began __ __/__ __/__ __ __ __	Date of last use __ __/__ __/__ __ __ __

HIV Testing History (record all dates as mm/dd/yyyy)

Main source of testing history information (select one)
☐ Patient interview ☐ Medical record review ☐ Provider report ☐ NHM&E ☐ Other

Date patient reported information __ __/__ __/__ __ __ __

Ever had previous positive HIV test? ☐ Yes ☐ No ☐ Unknown **Date of first positive HIV test** __ __/__ __/__ __ __ __

Ever had a negative HIV test? ☐ Yes ☐ No ☐ Unknown **Date of last negative HIV test** *(if date is from a lab test with test type, enter in Lab Data section)* __ __/__ __/__ __ __ __

Number of negative HIV tests within the 24 months before the first positive test __ __ ☐ Unknown

Comments

*Local/Optional Fields

This report to CDC is authorized by law (Sections 304 and 306 of the Public Health Service Act, 42 USC 242b and 242k). Response in this case is voluntary for federal government purposes, but may be mandatory under state and local statutes. Your cooperation is necessary for the understanding and control of HIV. Information in CDC's National HIV Surveillance System that would permit identification of any individual on whom a record is maintained, is collected with a guarantee that it will be held in confidence, will be used only for the purposes stated in the assurance on file at the local health department, and will not otherwise be disclosed or released without the consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 USC 242m).

Connecticut Department of Public Health
TB, HIV, STD and Viral Hepatitis Programs

Informed Consent to HIV Antibody Test*

HIV: Human Immunodeficiency Virus

Before you receive an HIV antibody test, you must give your consent. This form explains the test and how the test results can be used. It should help you decide whether you want to take the test. Please read it carefully. Your doctor or HIV tester must go over this information with you. If you have any questions, ask them. Please read all this information before you decide to be tested. If you want to be tested, please sign the back of this form.

What is the HIV Antibody Test?
It is a test that shows if you have either antibodies or antigen (or both) caused by HIV in your body. (HIV antibodies and antigen are a sign that HIV has entered your body.) A blood (fingerstick/ venipuncture) or oral sample will be taken from you and be tested. If the first test shows that you have the antibodies or antigen, a different test will be done to make sure the first test was right.

What does it mean if the test is Non-Reactive?
A non-reactive test means you're probably not infected with HIV. But it takes the body time to produce the HIV antibodies. It may just be too soon for the antibodies to be seen in the test. If you recently had sex without a condom or shared needles with someone who may be infected, you may want to be tested again in three to six months. Please talk to your doctor or HIV tester about this.

What does it mean if the confirmatory test is Reactive?
A reactive confirmatory test result means you are infected with HIV. It doesn't necessarily mean you have AIDS, but HIV is the virus that causes AIDS. It also means you could give the virus to other people. People who are infected can pass the virus during sex or by sharing needles during drug use. A pregnant woman who is infected can pass the virus to her baby during pregnancy or childbirth.

How will the test help me?
If the test is ***Non-Reactive***:

- Your doctor or HIV tester will discuss how to keep you from getting HIV in the future.

If the test is ***Reactive***:

- Your doctor can take better care of you by knowing your test result.
- You can learn about ways to stay healthy and new medicines that may help.
- You can learn how to avoid passing HIV to others.
- If you are pregnant, your doctor can give you and your baby special care and advice.
- Your test result is reported to the state health department using your name.

Do I have to take the test?
No. Taking the test is up to you. In most cases, you can't be made to take the HIV antibody test. If you don't want the test, you can still get medical care. But sometimes it may be harder for your doctor to give you the best care. If you want to take the test, you don't have to let anyone know your test result. You don't even have to tell anyone you've taken the test. You can find a testing site near you by calling **Infoline** at 211 or 1-800-203-1234 within Connecticut.

Do I have to tell anyone my test result?
If you take the test, your result is private. Under Connecticut law, only the people listed on the back of this form may have the result. (Please be sure to read the back of this form and ask your doctor or HIV tester if you have any questions.) If your test is positive, your sex and needle-sharing partners need to know. This is true for past and present partners. There is a special program that can help you tell your partners. If you are unable to tell partners yourself, they may be told, and your name won't be used.

What if I don't show up for my result?
By signing this consent form you give permission to the STD/HIV clinic to give your name to the Department of Public Health's Partner Services staff for the purpose of follow-up. Staff may follow-up with you for a period of up to thirty-six months for the purpose of informing you of your HIV test result or to locate you to ask you to return for your test results.

Should I tell anyone I've taken the test?
Who you tell is up to you. Something to consider is that some people who have AIDS or HIV, or have been tested for HIV have been treated unfairly. If you are discriminated against in a job, housing, public accommodation, or in getting credit, you may file a complaint with the Connecticut Commission on Human Rights & Opportunities. Call the Commission office in Hartford at (860) 541-3400 to find out the office that handles complaints for your area.

How can I get more information about the test and my rights?
If you have more questions about the test, please ask your doctor or call your local health department. If you have questions about your rights, contact the Connecticut Commission on Human Rights & Opportunities at (860) 541-3400.

WHO CAN RECEIVE HIV TEST RESULTS?
Under Connecticut law, HIV antibody test results and other AIDS information are private and may be given only:

1. To you (or a person authorized by law who agreed to the test for you);
2. To anyone you give written consent to get the test result;
3. To a health care facility (such as a hospital, blood bank or laboratory) that is giving health care to you or your child. HIV and AIDS information may also be recorded in your medical chart or records;
4. To a health care provider (such as a doctor or nurse) who is giving health care to you or your child;
5. To a committee or organization that reviews records in a health facility to monitor the care provided in that facility;
6. To insurance companies or government programs such as Medicaid if needed to pay for services you receive or for other types of claims such as a disability claim. (You may be able to pay for the test yourself if you don't want your insurance company to get your result.) If you are being tested for insurance, you can also choose a doctor or other health care provider who would receive your test result if it is positive;
7. To a person who gets a court order that gives them the right to your test result (this can only happen in special cases);
8. To a state institution (such as a correctional facility or state mental hospital), where employees may have the information in special cases;
9. To a health care worker or other type of worker who is exposed to your blood (in limited cases, such as sexual assault);
10. To a medical examiner;
11. To a public health officer if permitted by law.

All these people are also required by state law to keep your result private. You can ask your doctor or health care provider if your HIV test result has been released to anyone.

****

I have read all of this form or it has been read to me, and I've discussed it with my doctor or test counselor. I have been told about the nature of HIV and AIDS and have been told about how the virus may be passed from one person to another. I understand that testing HIV positive in Connecticut is reportable to the state health department and that if I test positive, the HIV tester will be reported by name. If I do not return for my test result, the test counselor will still report the result to the state health department.

I agree to take the HIV antibody test.

_____ _____

Name of person who will be tested *Date of birth*

_____ _____

Signature of person who will be tested or person authorized to consent for person *Date*

If someone other than the person to be tested has signed, give name and address of person signing and relationship to person to be tested. If necessary, explain why the person to be tested did not sign.

_____

I have provided to the person who signed this form an explanation of the nature of HIV and AIDS, information about behaviors known to pose risks for transmission of HIV infection, and discussed and answered any questions about the information covered in this form.

_____

Name of clinician or HIV tester

_____ _____

Signature of clinician or HIV tester *Date*

Connecticut Department of Public Health
TB, HIV, STD and Viral Hepatitis Programs

Informed Consent to HIV Antibody Test*

HIV: Human Immunodeficiency Virus

Before you receive an HIV antibody test, you must give your consent. This form explains the test and how the test results can be used. It should help you decide whether you want to take the test. Please read it carefully. Your doctor or HIV tester must go over this information with you. If you have any questions, ask them. Please read all this information before you decide to be tested. If you want to be tested, please sign the back of this form.

What is the HIV Antibody Test?
It is a test that shows if you have either antibodies or antigen (or both) caused by HIV in your body. (HIV antibodies and antigen are a sign that HIV has entered your body.) A blood (fingerstick/ venipuncture) or oral sample will be taken from you and be tested. If the first test shows that you have the antibodies or antigen, a different test will be done to make sure the first test was right.

What does it mean if the test is Non-Reactive?
A non-reactive test means you're probably not infected with HIV. But it takes the body time to produce the HIV antibodies. It may just be too soon for the antibodies to be seen in the test. If you recently had sex without a condom or shared needles with someone who may be infected, you may want to be tested again in three to six months. Please talk to your doctor or HIV tester about this.

What does it mean if the confirmatory test is Reactive?
A reactive confirmatory test result means you are infected with HIV. It doesn't necessarily mean you have AIDS, but HIV is the virus that causes AIDS. It also means you could give the virus to other people. People who are infected can pass the virus during sex or by sharing needles during drug use. A pregnant woman who is infected can pass the virus to her baby during pregnancy or childbirth.

How will the test help me?
If the test is ***Non-Reactive***:

- Your doctor or HIV tester will discuss how to keep you from getting HIV in the future.

If the test is ***Reactive***:

- Your doctor can take better care of you by knowing your test result.
- You can learn about ways to stay healthy and new medicines that may help.
- You can learn how to avoid passing HIV to others.
- If you are pregnant, your doctor can give you and your baby special care and advice.
- Your test result is reported to the state health department using your name.

Do I have to take the test?
No. Taking the test is up to you. In most cases, you can't be made to take the HIV antibody test. If you don't want the test, you can still get medical care. But sometimes it may be harder for your doctor to give you the best care. If you want to take the test, you don't have to let anyone know your test result. You don't even have to tell anyone you've taken the test. You can find a testing site near you by calling **Infoline** at 211 or 1-800-203-1234 within Connecticut.

Do I have to tell anyone my test result?
If you take the test, your result is private. Under Connecticut law, only the people listed on the back of this form may have the result. (Please be sure to read the back of this form and ask your doctor or HIV tester if you have any questions.) If your test is positive, your sex and needle-sharing partners need to know. This is true for past and present partners. There is a special program that can help you tell your partners. If you are unable to tell partners yourself, they may be told, and your name won't be used.

What if I don't show up for my result?
By signing this consent form you give permission to the STD/HIV clinic to give your name to the Department of Public Health's Partner Services staff for the purpose of follow-up. Staff may follow-up with you for a period of up to thirty-six months for the purpose of informing you of your HIV test result or to locate you to ask you to return for your test results.

Should I tell anyone I've taken the test?
Who you tell is up to you. Something to consider is that some people who have AIDS or HIV, or have been tested for HIV have been treated unfairly. If you are discriminated against in a job, housing, public accommodation, or in getting credit, you may file a complaint with the Connecticut Commission on Human Rights & Opportunities. Call the Commission office in Hartford at (860) 541-3400 to find out the office that handles complaints for your area.

How can I get more information about the test and my rights?
If you have more questions about the test, please ask your doctor or call your local health department. If you have questions about your rights, contact the Connecticut Commission on Human Rights & Opportunities at (860) 541-3400.

WHO CAN RECEIVE HIV TEST RESULTS?
Under Connecticut law, HIV antibody test results and other AIDS information are private and may be given only:

1. To you (or a person authorized by law who agreed to the test for you);
2. To anyone you give written consent to get the test result;
3. To a health care facility (such as a hospital, blood bank or laboratory) that is giving health care to you or your child. HIV and AIDS information may also be recorded in your medical chart or records;
4. To a health care provider (such as a doctor or nurse) who is giving health care to you or your child;
5. To a committee or organization that reviews records in a health facility to monitor the care provided in that facility;
6. To insurance companies or government programs such as Medicaid if needed to pay for services you receive or for other types of claims such as a disability claim. (You may be able to pay for the test yourself if you don't want your insurance company to get your result.) If you are being tested for insurance, you can also choose a doctor or other health care provider who would receive your test result if it is positive;
7. To a person who gets a court order that gives them the right to your test result (this can only happen in special cases);
8. To a state institution (such as a correctional facility or state mental hospital), where employees may have the information in special cases;
9. To a health care worker or other type of worker who is exposed to your blood (in limited cases, such as sexual assault);
10. To a medical examiner;
11. To a public health officer if permitted by law.

All these people are also required by state law to keep your result private. You can ask your doctor or health care provider if your HIV test result has been released to anyone.

****

I have read all of this form or it has been read to me, and I've discussed it with my doctor or test counselor. I have been told about the nature of HIV and AIDS and have been told about how the virus may be passed from one person to another. I understand that testing HIV positive in Connecticut is reportable to the state health department and that if I test positive, the HIV tester will be reported by name. If I do not return for my test result, the test counselor will still report the result to the state health department.

I agree to take the HIV antibody test.

_____ _____

Name of person who will be tested *Date of birth*

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_____

Name of clinician or HIV tester

_____ _____

Signature of clinician or HIV tester *Date*

Connecticut Department of Public Health
TB, HIV, STD and Viral Hepatitis Programs

*Consentimiento para el examen de anticuerpos del VIH**

***HIV: Virus de Immunodeficiencia Humana que causa el SIDA.**

Antes de que alguien le haga la prueba o examen para detectar anticuerpos del VIH, Ud. debe dar su consentimiento. Este formulario explica dicho examen y como se pueden utilizar los resultados del mismo. Le ayudará a decidir si desea hacerse la prueba o no. Lea este folleto cuidadosamente. Su doctor o consejero médico debe repasar esta infomación con Ud. Si tiene dudas, pregúntele. Lea esta información antes de tomar una decisión. Si desea hacerse la prueba, firme la parte de atrás de este formulario.

¿Qué es el examen de anticuerpos del VIH?

Se trata de un examen de la sangre, el cual muestra si Ud. tiene anticuerpos del virus del SIDA (La presencia de anticuerpos del VIH es un sintoma de que el virus ha entrado al cuerpo.) Una muestra de sangre o fluido oral le será tomada para analysis Si el primer examen muestra que Ud. tiene los anticuerpos, se le hará un examen diferente en la misma muestra para asegurarse que el resultado del primer examen es correcto.

¿Qué pasa si el resultado es negativo?

Un resultado negativo significa que probablemente Ud. no se ha infectado con el VIH. Sin embargo, toma tiempo para que el cuerpo produzca los anticuerpos del VIH. Puede que sea muy pronto para que estos anticuerpos sean detectados en el examen. Si recientenmente Ud. tuvo relaciones sexuales sin condón o compartió jeringas con alguien que podria estar infectado, es recomendable que se haga el examen de nuevo dentro de tres a seis meses. Consulte acerca de esto con su doctor o consejero medico.

¿Qué pasa si el resultado es positivo?

Un resultado positivo significa que Ud. se ha infectado con el VIH. Esto no necesariamente significa que usted tiene SIDA. Sin embargo, muchas personas que tienen el virus se enferman con el paso del tiempo.

También significa que Ud. puede transmitir el virus a otras personas, ya que las personas infectadas pueden transmitir el virus al tener relaciones sexuales o al cornpartir jeringas para el uso de drogas. Las mujeres embarazadas que están infectadas con el virus pueden tramsmitirlo a sus bebés durante el embarazo.

¿En qué forma puede ayudarme el examen?

Si el resultado es *negativo:*

Su doctor o consejero médico le explicará cómo evitar contraer el VIH en el futuro.

Si el resultado es *positivo:*

- Su doctor le puede atender mejor si conoce el resultado del examen.
- Ud. puede aprender cómo mantenerse saludable y cómo usar nuevos medicamentos que podrían ayudarle.
- Ud. puede aprender cómo evitar la transmisión del VIH a otras personas.
- Si está embrazada, su doctor le puede brindar consejos y cuidados especiales a Ud. y a su bebé.
- Es reportado al Departamento de Salud del estado por nombre.

¿Tengo que hacerme el examen?

No. El examen es voluntario y en la mayoría de las casos, no se le puede obligar a que se haga el examen de anticuerpos del VIH.

Si no desea hacerse el examen, aun puede reciber atención médica. Sin embargo, a veces esto puede evitar que Ud. reciba el cuidado adecuado.

Si desea hacerse el examen, no tiene que informar el resultado a nadie. Ni siquiera tiene que decir que se lo ha hecho. Existen centros donde puede hacerse el examen sin dar su nombre. Puede llamar a Infoline al 1-800-203-1234 o al 211 dentro de la zona de Connecticut para obtener información acerca del centro más cercano. Es probable que no pueda hacerse este tipo de examen en un hospital o en algunos otros centros médicos.

¿Tengo que informar a alguien del resultado del examen?

Si se hace el examen, el resultado es confidencial. Bajo la ley de Connecticut, únicamente la personas mencionadas en la parte de atrás de este formulario pueden saber el resultado. (Asegúrese de leer la parte de atrás de este formulario y de preguntar a su doctor o consejero médico si tiene dudas.)

Si el resultado es positivo, debe informarle a las personas con quienes ha tenido contacto sexual o con quienes ha compartido jeringas. Esto incluye a personas en el presente y en el pasado. Existe un programa especial que puede ayudarle a informarles, y si Ud. no desea hacerlo personalmente, se les puede informar sin mencionar su nombre.

¿Qué pasa si no regreso para obtener el resultado?

Al firmar este formulario de consentimiento. Ud. otorga permiso a la clinica ETS/VIH para que informe al Disease Intervention Specialist (DIS) del Departamento de Salud Pública con el fin de hacer un seguimiento por un periodo de treinta y seis meses para informarle del resultado del examen de VIH o para pedirle que regrese a la clinica a obtener el resultado.

¿Debo informar a alguien que me he hecho el examen?

Debe tener cuidado al infomar a otros que se ha hecho el examen. Algunas personas que tienen SIDA o el VIH – o que sólo se han hecho el examen - han sido tratados de manera injusta. Si se le ha discriminado en su centro de empleo, vivienda, centro público o al obtener credito, puede presentar

una queja a la Comisión de Derechos Humanos y Oportunidades de Connecticut. Llame a la oficina de la Comisión en Hartford al (860) 541-3400 para obtener información acerca de la oficina que tramita las quejas en su área.

¿Cómo puedo obtener mayor información acerca del examen y mis derechos?
Si tiene más preguntas acerca del examen, consulte con su doctor o llame al departamento de salud local. Si tiene preguntas acerca de sus derechos, llame a la Comisión de Derechos Humanos y Oportunidades de Connecticut al (860) 541-3400 or al 1-800-477-5737 (si llama desde Connecticut).

¿QUIÉN PUEDE OBTENER LOS RESULTADOS DEL EXAMEN DEL SIDA?
Bajo la ley de Connecticut, el resultado del examen de anticuerpos del VIH y cualquier otra información concerniente al SIDA es confidencial y puede dársele sólo a:

1. Usted (o a una persona autorizada por la ley quien dio consentimiento para el examen en su nombre);
2. Cualquier persona que posea su consentimiento por escrito para obtener el resultado;
3. Un centro de cuidado medico (como un hospital, banco de sangre o laboratorio) ha hecho el examen. Algunas personas que tienen SIDA o el virus del que esté brindando atención medica a Ud. o a su hijo(a). La infomación concerniente al VIH y al SIDA puede tambien registrarse en su ficha o archivo medico;
4. Un proveedor de cuidado médico (como un doctor o enfermera) que esté brindando atención médica a Ud. o a su hijo(a);
5. Un comité u organización que analiza Ios registros en un centro médico para supervisar el cuidado brindado en dicho centro;
6. Compañías de seguros o programas gubernamentales como "Medicaid" si éstos lo requieren para efectuar pagos por servicios recibidos por Ud. o para otros tipos de reclamaciones tales como reclamaciones de incapacidad. (Es probable que Ud. pueda pagar el examen si no desea que la compañías de seguros obtengan el resultado.) Si se hace el examen debido a un seguro, puede elegir a un doctor o proveedor de cuidado médico para que éste reciba el resultado si es positivo;
7. Una persona que obtenga una orden de la corte que le otorgue el derecho de obtener el resultado (esto sólo sucede en casos excepcionales);
8. Una instiución estatal (tal como un centro correccional u hospital mental estatal), donde los empleados puedan obtener la información en casos especiales;
9. Un empleado de un centro de cuidado médico u otro tipo de empleado que tiene contacto con su sangre (en casos limitados, tal como un asalto sexual);
10. Un examinador médico;
11. Un oficial de salud pública si la ley lo permite.

La ley del estado también requiere que todas estas personas mantengan la infomiación en forma confidencial.
Puede preguntar a su doctor o proveedor de cuidado médico si se ha infonnado a alguien el resultado del examen del virus del SIDA (VHI).

He leído o se me ha leído toda la información que se encuentra en este formulario y la he discutido con mi doctor o consejero médico. Se me ha explicado la naturaleza del VIH, y se me ha informado de la manera en que se transmite dicho virus de una persona a otra. Entiendo que ser VIH positive en Connecticut se reporta al Departamento de Salud del estado y que si tengo un resultado positive, es reporlado por nombre. Si no regreso a recoger los resultados de mi prueba, el consejero, enfermero o médico reportará mi resultado positive por nombre al Departamento de Salud del estado.
Estoy de acuerdo en hacerme el examen de anticuerpos del VIH.

_____ _____

Nombre de la persona a la que se administrará el examen *Fecha de nacimiento*

_____ _____

Firma de la persona que se hará el examen o de quien tiene autorización para dar consentimiento en nombre de dicha persona. *Fecha*

Si el firmante no es la persona que se va a hacer el examen, indique el nombre y dirección del firmante y su relación con dicha persona. De ser necesario, explique las razones por las cuales esta persona no puede firmar.

_____

He explicado al firmante de este formulario acerca de la naturaleza del VIH, el SIDA y las enfermedades relacionadas con el VIH, asimismo, le he informado del tipo de comportamiento que puede llevar a la de transmisión del VIH, y he discutido y contestado las preguntas hechas en cuanto a la información cubierta en este formulario.

_____

Nombre def doctor o consejero médico

_____ _____

Firma del doctor o consejero médico *Fecha*

Connecticut Department of Public Health
TB, HIV, STD and Viral Hepatitis Programs

*Consentimiento para el examen de anticuerpos del VIH**

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¿Qué es el examen de anticuerpos del VIH?

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¿Qué pasa si el resultado es negativo?

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¿En qué forma puede ayudarme el examen?

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- Ud. puede aprender cómo mantenerse saludable y cómo usar nuevos medicamentos que podrían ayudarle.
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¿Tengo que hacerme el examen?

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¿Tengo que informar a alguien del resultado del examen?

Si se hace el examen, el resultado es confidencial. Bajo la ley de Connecticut, únicamente la personas mencionadas en la parte de atrás de este formulario pueden saber el resultado. (Asegúrese de leer la parte de atrás de este formulario y de preguntar a su doctor o consejero médico si tiene dudas.)

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3. Un centro de cuidado medico (como un hospital, banco de sangre o laboratorio) ha hecho el examen. Algunas personas que tienen SIDA o el virus del que esté brindando atención medica a Ud. o a su hijo(a). La infomación concerniente al VIH y al SIDA puede tambien registrarse en su ficha o archivo medico;
4. Un proveedor de cuidado médico (como un doctor o enfermera) que esté brindando atención médica a Ud. o a su hijo(a);
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8. Una instiución estatal (tal como un centro correccional u hospital mental estatal), donde los empleados puedan obtener la información en casos especiales;
9. Un empleado de un centro de cuidado médico u otro tipo de empleado que tiene contacto con su sangre (en casos limitados, tal como un asalto sexual);
10. Un examinador médico;
11. Un oficial de salud pública si la ley lo permite.

La ley del estado también requiere que todas estas personas mantengan la infomiación en forma confidencial.
Puede preguntar a su doctor o proveedor de cuidado médico si se ha infonnado a alguien el resultado del examen del virus del SIDA (VHI).

He leído o se me ha leído toda la información que se encuentra en este formulario y la he discutido con mi doctor o consejero médico. Se me ha explicado la naturaleza del VIH, y se me ha informado de la manera en que se transmite dicho virus de una persona a otra. Entiendo que ser VIH positive en Connecticut se reporta al Departamento de Salud del estado y que si tengo un resultado positive, es reporlado por nombre. Si no regreso a recoger los resultados de mi prueba, el consejero, enfermero o médico reportará mi resultado positive por nombre al Departamento de Salud del estado.
Estoy de acuerdo en hacerme el examen de anticuerpos del VIH.

_____ _____
Nombre de la persona a la que se administrará el examen *Fecha de nacimiento*

_____ _____
Firma de la persona que se hará el examen o de quien tiene autorización para dar consentimiento en nombre de dicha persona. *Fecha*

Si el firmante no es la persona que se va a hacer el examen, indique el nombre y dirección del firmante y su relación con dicha persona. De ser necesario, explique las razones por las cuales esta persona no puede firmar.

_____
He explicado al firmante de este formulario acerca de la naturaleza del VIH, el SIDA y las enfermedades relacionadas con el VIH, asimismo, le he informado del tipo de comportamiento que puede llevar a la de transmisión del VIH, y he discutido y contestado las preguntas hechas en cuanto a la información cubierta en este formulario.

_____
Nombre def doctor o consejero médico

_____ _____
Firma del doctor o consejero médico *Fecha*

EvaluationWeb® 2018 HIV Test Template

Form ID *(enter or adhere)*

1 Agency and Client Information
(complete for ALL persons)

Session Date

Program Announcement
- ○ PS15-1506 PrIDE
- ○ PS15-1509 THRIVE
- ○ PS17-1711
- ○ PS18-1802
- ○ PS18-1802 Demonstration Projects
- ○ PS19-1901 CDC STD
- ○ Other CDC funded
- ○ Other non-CDC funded

Specify Other *(optional)*

Agency Name or ID

Site Name or ID

Site Type *(codes below)*

Site ZIP Code

Site County *(3-digit FIPS code)*

Local Client ID *(optional)*

Year of Birth *(1800 if unknown)*

Client State *(USPS abbreviation)*

Client County *(3-digit FIPS code)*

Client ZIP Code

Client Ethnicity
- ○ Hispanic or Latino
- ○ Not Hispanic or Latino
- ○ Don't know
- ○ Declined to Answer

Client Race *(select all that apply)*
- ☐ American Indian/Alaska Native
- ☐ Asian
- ☐ Black/African American
- ☐ Native Hawaiian/Pacific Islander
- ☐ White
- ☐ Not Specified
- ☐ Declined to Answer
- ☐ Don't Know

Client Assigned Sex at Birth
- ○ Male
- ○ Female
- ○ Declined to Answer

Client Current Gender Identity
- ○ Male
- ○ Female
- ○ Transgender Male to Female
- ○ Transgender Female to Male
- ○ Transgender Unspecified
- ○ Another Gender
- ○ Declined to Answer

Has the client had an HIV test previously?
- ○ No
- ○ Yes
- ○ Don't Know

Site Types: Clinical
- F01.01 - Inpatient hospital
- F02.12 - TB clinic
- F02.19 - Substance abuse treatment facility
- F02.51 - Community health center
- F03 - Emergency department
- F08 - Primary care clinic (other than CHC)
- F09 - Pharmacy or other retail-based clinic
- F10 - STD clinic
- F11 - Dental clinic
- F12 - Correctional facility clinic
- F13 - Other

Site Types: Mobile
- F40 - Mobile Unit

Site Types: Non-clinical
- F04.05 - HIV testing site
- F06.02 - Community setting - School/educational facility
- F06.03 - Community setting - Church/mosque/synagogue/temple
- F06.04 - Community Setting - Shelter/transitional housing
- F06.05 - Community setting - Commercial facility
- F06.07 - Community setting - Bar/club/adult entertainment
- F06.08 - Community setting - Public area
- F06.12 – Community setting – Individual residence
- F06.88 - Community setting - Other
- F07 - Correctional facility - Non-healthcare
- F14 - Health department - Field visit
- F15 - Community Setting - Syringe exchange program
- F88 - Other

Form Approved: OMB No. 0920-0696, Exp. 10/31/2021. Public reporting burden of this collection of information is estimated to average 8 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-79, Atlanta, Georgia, 30333, ATTN: PRA 0920-0696. CDC 50.135b(E),10/2007

EvaluationWeb® 2018 HIV Test Template

Form ID *(enter or adhere)*

2 Final Test Information
(complete for ALL persons)

HIV Test Election
○ Anonymous ○ Confidential ○ Test Not Done

Test Type *(select one only)*
○ CLIA-waived point-of-care (POC) Rapid Test(s)
○ Laboratory-based Test

POC Rapid Test Result *(definitions on page 3)*	Laboratory-based Test
○ Preliminary Positive	○ HIV-1 Positive
○ Positive	○ HIV-1 Positive, possibly acute
○ Negative	○ HIV-2 Positive
○ Discordant	○ HIV Positive, undifferentiated
○ Invalid	○ HIV-1 Negative, HIV-2 Inconclusive
	○ HIV-1 Negative
	○ HIV Negative
	○ Inconclusive, further testing needed

Result provided to client?
○ No ○ Yes ○ Yes, client obtained the result from another agency

3 Negative Test Result
(complete for persons testing NEGATIVE for HIV)

Is the client at risk for HIV infection? (*optional*)
○ No ○ Yes ○ Risk Not Known ○ Not Assessed

Was the client screened for PrEP eligibility?
○ No ○ Yes

Is the client eligible for PrEP referral?
○ No ○ Yes, by CDC criteria ○ Yes, by local criteria or protocol

Was the client given a referral to a PrEP provider?
○ No ○ Yes

Was the client provided with services to assist with linkage to a PrEP provider?
○ No ○ Yes

4 Positive Test Result
(complete for persons testing POSITIVE for HIV)

Did the client attend an HIV medical care appointment after this positive test?
○ Yes, confirmed ○ No
○ Yes, client/patient self-report ○ Don't Know
→ Date Attended

Has the client ever had a positive HIV test?
○ No ○ Yes ○ Don't Know
→ Date of first positive result

Was the client provided with individualized behavioral risk-reduction counseling?
○ No ○ Yes

Was the client's contact information provided to the health department for Partner Services?
○ No ○ Yes

What was the client's most severe housing status in the last 12 months?
○ Literally homeless ○ Not asked
○ Unstably house or at risk of losing housing ○ Declined to Answer
○ Don't know
○ Stably housed

If the client is female, is she pregnant?
○ No ○ Declined to Answer
○ Yes ○ Don't know

→ Is the client in prenatal care?
○ No ○ Don't know ○ Not asked
○ Yes ○ Declined to Answer

→ Was the client screened for need of perinatal HIV service coordination?
○ No ○ Yes

→ Does the client need perinatal HIV service coordination?
○ No ○ Yes

→ Was the client referred for perinatal HIV service coordination?
○ No ○ Yes

EvaluationWeb® 2018 HIV Test Template

Form ID *(enter or adhere)*

5 Additional Tests
(complete for ALL persons)

Was the client tested for co-infections?

○ No ○ Yes

Tested for Syphilis?

○ No ○ Yes

Syphilis Test Result *(optional)*
- ○ Newly Identified infection
- ○ Not Infected
- ○ Don't know

Tested for Gonorrhea?

○ No ○ Yes

Gonorrhea Test Result *(optional)*

○ Positive ○ Negative ○ Don't Know

Tested for Chlamydial infection?

○ No ○ Yes

Chlamydial infection Test Result *(optional)*

○ Positive ○ Negative ○ Don't Know

Tested for Hepatitis C?

○ No ○ Yes

Hepatitis C Test Result *(optional)*

○ Positive ○ Negative ○ Don't Know

Value Definitions for POC Rapid Test Results

Preliminary positive - One or more of the same point-of-care rapid tests were reactive and none are non-reactive and no supplemental testing was done at your agency

Positive - Two or more different (orthogonal) point-of-care rapid tests are reactive and none are non-reactive and no laboratory-based supplemental testing was done

Negative - One or more point-of-care rapid tests are non-reactive and none are reactive and no supplemental testing was done

Discordant - One or more point-of-care rapid tests are reactive and one or more are non-reactive and no laboratory- based supplemental testing was done

Invalid - A CLIA-waived POC rapid test result cannot be confirmed due to conditions related to errors in the testing technology, specimen collection, or transport

6 PrEP Awareness and Use/Priority Populations
(complete for all persons)

Has the client ever heard of PrEP (Pre-Exposure Prophylaxis)?

○ No ○ Yes

Is the client currently taking daily PrEP medication?

○ No ○ Yes

Has the client used PrEP anytime in the last 12 months?

○ No ○ Yes

In the past five years, has the client had sex with a male?

○ No ○ Yes

In the past five years, has the client had sex with a female?

○ No ○ Yes

In the past five years, has the client had sex with a transgender person?

○ No ○ Yes

In the past five years, has the client injected drugs or substances?

○ No ○ Yes

7 Essential Support Services
(complete for all persons, EXCEPT as indicated)

	Screened for need	Need determined	Provided or referred
Navigation services for linkage to HIV medical care *(positive only)*	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Linkage services to HIV medical care *(positive only)*	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Medication adherence support *(positive only)*	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Health benefits navigation and enrollment	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Evidence-based risk reduction intervention	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Behavioral health services	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Social services	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes

EvaluationWeb® 2018 HIV Test Template

Form ID *(enter or adhere)*

8 Local Use Fields *(optional)*

Local Use Field 1
Local Use Field 2
Local Use Field 3
Local Use Field 4
Local Use Field 5
Local Use Field 6
Local Use Field 7
Local Use Field 8

Notes *(optional)*

9 Health Department Use Only *(complete for persons testing POSITIVE for HIV)*

eHARS State Number

eHARS City/County Number

New or Previous diagnosis?

- ○ New diagnosis, verified
- ○ New diagnosis, not verified
- ○ Previous diagnosis
- ○ Unable to determine

Has the client seen a medical care provider in the past six months for HIV treatment?

- ○ No
- ○ Yes
- ○ Declined to Answer
- ○ Don't know

Partner Services Case Number

Was the client interviewed for Partner Services?

- ○ Yes, by a health department specialist
- ○ Yes, by a non-health department person trained by the health department to conduct partner services
- ○ No
- ○ Don't Know

Date of Interview

Value Definitions for POC Rapid Test Results

New diagnosis, verified - The HIV surveillance system was checked and no prior report was found and there is no indication of a previous diagnosis by either client self report (if the client was asked) or review of other data sources (if other data sources were checked).

New diagnosis, not verified - The HIV surveillance system was not checked and the classification of new diagnosis is based only on no indication of a previous positive HIV test by client self-report or review of other data sources.

Previous diagnosis - Previously reported to the HIV surveillance system or the client reports a previous positive HIV test or evidence of a previous positive test is found on review of other data sources.

Unable to determine - The HIV surveillance system not checked and no other data sources were reviewed and there is no information from the client about previous HIV test results.

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Deidre S. Gifford, MD, MPH
Acting Commissioner

Ned Lamont
Governor

Susan Bysiewicz
Lt. Governor

CT Department of Public Health (DPH) Policy

for In-Home HIV Test Initiative

Background:

Prevention services are a vital component in Public Health. High Impact Prevention (HIP) services, such as HIV Testing, Referral, and Linkage have proven to be the cornerstone in reducing HIV in populations most at risk. COVID-19 has dramatically altered the way we provided prevention services in Connecticut and the need to implement strategies to meet communities hardest hit by HIV is critical during this time. In March 2020, CT DPH launched the **Free In-Home HIV Test initiative,** *#RequestFreeHIVTestCT*, as a pilot to enhance access to HIV testing for hard to reach populations, such as LGBTQ, and people of color. The In-Home HIV Test Kit is an oral-swab rapid HIV test, that is self-administered in the privacy of one's home. The pilot began in March 2020 and the number of organizations participating continues to grow. In the spirit of true harm reduction philosophy, the initiative aims to meet people where they are. CT DPH HIV Prevention Program is committed to working with our community providers to continue to provide access to the prevention services during challenging times.

Purpose:

The purpose of this policy is to assist participating organizations/agencies in developing their own In-Home HIV Test program. This policy provides information on how to request the In-Home HIV Test Kits, how to market the program using the CT DPH social media/marketing materials, how to collect data to report to CT DPH, and how to access additional resources and materials.

Phone: (860) 509-7801 • Fax: (860) 509-7853
Telecommunications Relay Service 7-1-1 410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308 www.ct.gov/dph
Affirmative Action/Equal Opportunity Employer

Policy Guidance:

To make this pilot initiative most efficient for public health, the DPH has developed the following guidance policy: CT DPH has centralized system for participating partner agencies to order In-Home HIV Test Kits for distribution to their clients at no cost to the clients**.**

For Agencies to Request to Participate in the Pilot Program (Develop your own In-Home HIV Test Program/Initiative):

- Agencies will send a 'Request to Participate' email to Venesha Heron and request the number of box(es) of kits based on their agency's needs and capacity to distribute to clients.
- Agencies will then arrange to pick up the In-Home HIV Test kits from DPH.
- CT DPH will provide each agency with a policy guidance and additional resources and materials to support their development and marketing of their own In-Home HIV Test program/initiative, as well as how collect and report the data to the DPH.

For Clients to Request Free In-Home HIV Test kit from Partnering Agencies or from the DPH:

- Clients are engaged through the DPH social media campaigns and by participating agencies' social media platforms.
- To request the Free In-Home HIV test kit, there are two methods a person could use to access the CT DPH In-Home Test Kit Request Form (i.e., via SurveyMonkey). First, by visiting: **tinyurl.com/RequestFreeHIVtestCT**. Second, by scanning a 'QR code' that directs them to the SurveyMonkey.
- Access to the required CT DPH In-Home Test Kit Request Form (i.e., via SurveyMonkey), using either **tinyurl.com/requestfreehivtestct** or the provided QR code (see Fig 1).

Fig 1. Tinyurl and QR Code

*****Note to agencies and clients:**

- DPH requires all clients or an agency tester/counselor, on behalf of the client, to fill out the CT DPH InHome Test Kit Request Form prior to mailing or providing the client(s) with the kits.
- If eligible (being a CT resident and not previously testing positive for HIV), clients will be mailed an InHome HIV Test Kit. HIV test kits are manufactured by OraQuick Technologies and are shipped in **confidential** and **discreet** packaging. The kit includes easy to read instructions and if needed, a telephone number for any questions about the test.
- In-Home HIV Test kits can also be hand-delivered to clients in a **confidential** and **discreet** manner, to safeguard the client(s) privacy and confidentiality.
- Per OraSure Technologies, the manufacturer of the In-Home HIV Test Kits, during COVID-19 pandemic, the In-Home HIV tests can also be administered in a rapid HIV test session manner, in a safe, secure and confidential setting, while adhering to social distancing (COVID-19 pandemic shelter in place/social distance orders). See video link attached for information on Innovative Strategies for HIV Screening During COVID-19: https://www.youtube.com/watch?v=kosVja3t6YQ&feature=youtu.be [time: 9:34]

Marketing and Promotion:

- Participating agencies will create, customize, or use the DPH campaign using #RequestFreeHIVTestCT messaging campaign on agency social platforms or other outreach methods to the community, and will submit to DPH for review. The tiny url (i.e., **tinyurl.com/requestfreehivtestct)** and the QR code to the CT DPH In-Home Test Kit Request Form (i.e., via SurveyMonkey) can be used on agencies' promotional materials.
- Participating agencies will use share these materials on their respective social networking apps like Facebook, Instagram, agency webpage, Grindr, etc., to engage these hard to reach populations (clients).
- Participating agencies will develop and submit an In-Home HIV Test Program Policy and Protocol to DPH for review. (This Policy and Protocol can be revised to reflect improvements and best practices and send to DPH for review)

Data Collection, Reporting, and Quality Improvement:

- Data collection is key to determining who DPH is reaching with this initiative—data collection is very important to monitor and evaluate In-Home HIV testing activities and its outcomes
- Clients interested in the In-Home HIV Test initiative will use the CT DPH In-Home Test Kit Request Form (i.e., via SurveyMonkey), using either **tinyurl.com/requestfreehivtestct** or the provided QR code (see above figure 1).
- Participating agencies are also encouraged to conduct additional client's risk assessment besides the data that is required and reported via the SurveyMonkey for the purpose of providing additional referrals and linkages, should the clients have other needs. This data will be used for future decision making.

- Participating agencies are required report to DPH any narrative information on successes and challenges with the HIV Test Initiative in DPH Tri-Annual Reports.
- Participating agencies are required to report to DPH any issues regarding follow-up and engagement, especially for clients that self-report HIV reactive results.
- Participating agencies are also required to provide monthly reports to DPH on requested data variables
- The overall number of In-Home test kits distributed in Connecticut will be reported to the CDC aggregately, via EvaluationWeb.
- Agencies must develop their own agency protocols to submit to DPH for approval.

Confidentiality:

- All participating agencies shall adhere to the CT DPH Confidentiality and Security Standards when participating in any CT DPH pilot programs or initiatives. All testers who will be participating in the In Home HIV Test initiative must review the document in the hyperlink below: https://portal.ct.gov/-/media/DPH/HIV-Surveillance/CT-DPH-TB-HIV-STD-Viral-Hepatitis-Data-Security-andConfidentiality-Policy-and-Procedures-2020.pdf

- All participating organizations/agencies shall adhere to the CDC Principles for Data Collection, Storage, Sharing, and Use to Ensure Security and Confidentiality and protecting the privacy of clients served. https://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf

Mailing and Distribution:

- In-Home HIV Test kits requests can be fulfilled through USPS shipment
- The range for shipping/postage can be anywhere from $8.00 - $8.85 with delivery between 1-3 days
- Clients will be sent the In-Home HIV Test Kit within 1-2 business days of the request.
- The test kit includes detailed instructions; a video link demonstration on how to administer the test; information about non-reactive and reactive test results; confirmatory test information; PrEP, PEP; and U=U information. Agencies can also include other information and materials about HIV and STI prevention and care resources; condoms, lubrication packets and other informational materials as inserts.

Getting Results:

- Clients will get the results in the comfort of their own space/home, using an In-Home Test Kit within 20 minutes of administering the test.
- Agencies should make every effort to engage with clients to inform them to self-report test results within 1-2 weeks of receiving their test kit in the mail, and in a safe and confidential manner.
- Some clients may report back with their results, some may not. If not, the agency should conduct a courtesy follow-up via phone call or in a **secure** and **confidential** manner and document any information in a secured log or secured files within 2 weeks of shipping the In-Home HIV Test kits It is

each agency's responsibility to ensure that clients/patients have access to services and linkages if needed and document the nature of the services provided or requested.

- To report newly diagnosed HIV positives from the In-Home HIV Test Initiative, please refer to the **HIV/HCV Rapid Testing Case Reporting Guidance**

Resources:

Additional information about the #RequestFreeHIVTestCT initiative can be found below:

- The weblink to CT DPH In-Home Test Kit Request Form is **http://tinyurl.com/requestfreehivtestct**
- OraQuick home test kit materials: A PDF copy of the instruction card deck that is included with each test kit. When the participant opens the test kit, they will flip through the instruction cards, this PDF is a copy of those cards so that agency staff could review with the participant or use some of the graphics and instructions to assist in instructing the client.
- OraQuick provides access to videos and materials at **http://www.oraquick.com/** . The link below demonstrates instructions on how to take the test **http://www.oraquick.com/Taking-the-Test/HowTo-Video**
- Webinar recording: *Innovative Strategies for HIV Screening During COVID-19* **https://www.youtube.com/watch?v=kosVja3t6YQ&feature=youtu.be**

For more information, contact Project Lead, Venesha Heron at Venesha.heron@ct.gov. DPH values our agencies continued commitment to HIV prevention during the COVID-19 pandemic and will continue to work with community to develop and provide additional guidance, resources, and technical assistance (TA) to support reducing HIV in Connecticut.