PUBLIC SAFETY COVID-19 TESTING



Leading the search for tomorrow's cures









--A partnership between Innovative Technology and 1st Responders to improve public safety capabilities--

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1. USE OF DOCUMENT

The following document (Section 2 – Section 19) was produced to initiate the Town of West Hartford's Public Safety COVID Testing program. The original purpose was merely to establish a historical record for the Town when starting a new and unique program. To date, the testing program has been overwhelmingly successful for West Hartford and has received a significant amount of attention from first responder agencies across Connecticut and other stakeholders. The Town of West Hartford is very willing to assist any partner agency with establishing a program but notes that anyone seeking to create a similar program should carefully ensure that they have sought and obtained the appropriate permissions from the various entities at the CT Department of Public Health and their Sponsor Hospital Medical Control. Of important note, agencies should also pay close attention to the cost of the tests and who will be paying the laboratory fees. This program currently relies upon a financial system where tests costs are covered by the Town with a high expectation of reimbursement at a later date.

While certain sections of the original document has been updated, the substantial changes to the program between its inception and current date are summarized in Section 20. For all those who have reviewed this document previously, this section details many of the important changes that have been made. The Town of West Hartford, especially those responders and others who have been tested because of this program, would like to offer our distinct thanks all those who have assisted us getting started and maintaining it.

2. Original Purpose/Overview

In late 2019, a novel Coronavirus (COVID-19) began to circumnavigate the world and was later declared a pandemic by the World Health Organization. In March of 2020, COVID-19 was well-seated in the United States. Specifically, in the Connecticut area, numerous cases were documented, and the virus spread accelerated. Nationally, personal protective equipment (PPE) shortages, lack of availability of wide-spread COVID-19 testing and increasing cases of 1st responders contracting the virus or requiring quarantine hindered public safety pandemic response.

Faced with this unprecedented situation and a need to maintain a viable workforce of public safety personnel, public safety leaders and Town officials in West Hartford determined that the accelerated COVID19 testing of 1st responders is a critical need. Further, having encountered situations where family members of public safety employees had affected their availability, the need to have more control and testing capability was visible. The ability to rapidly decide who needs to be tested, obtain results and mitigate a positive COVID-19 within the 1st responder network will inform Town officials and public safety leadership as to the availability of their response forces. The result is the effectiveness of controlling the virus within West Hartford responders, thereby improving public safety within the Town.

While the availability of first responder testing has exponentially increased since the initial concept phase, through a collaboration with The Jackson Laboratory the Town of West Hartford will establish the Public Safety COVID Testing (PSCT) program. The PSCT will entail an administrative framework to determine the feasibility to provide expedited testing to responders or others domiciled with first responders. The primary focus of in-house testing will be protecting the inbound network that enables public safety employees to report to work. Under a protocol established by the West Hartford Fire Department's sponsor hospital medical control physician, a COVID test will be ordered. An electronic medical record (PCR) for the source patient will be generated. The PCR will act as consent for test as well

as provide a medium to attach test results. Licensed West Hartford Public Safety medical providers, trained in COVID specimen collection under defined parameters, will collect specimen(s). The specimen(s) are barcoded, documented and submitted to Jackson Laboratory for testing. Test results are securely transmitted back to an authorized point of contact (POC) for the Town to receive protected health information (PHI). The POC will ensure that the test results are communicated back to the source individual, Public Safety administrators with a need to know, the Health District, and then recorded in the source individual's medical record. In their capacity as a testing entity, the Jackson Laboratory is required to, and will report either "Detected SARS-CoV-2" or "Not Detected" results to the State Health Laboratory. Public Safety administrators in consultation with the Health District will be responsible for positive COVID resulted contact tracing of the individual. If medical care for source individual is needed, the source individual will be responsible for obtaining care through the Town's worker's compensation process (if applicable), their own personal care provider or other medical provider. The medical control physician for the WHFD and the PSCT will not be responsible for establishing a direct physician patient relationship.

The PSCT program will expand the amount of testing available to the 1st responders and improve public safety within West Hartford. Further, with the availability of COVID antibody testing on the horizon, the Town and its Public Safety Administration are very appreciative of the support and guidance of Mayor Shari Cantor and The Jackson Laboratory's President and CEO, Edison Liu as well as Police Captain Kevin McCarthy who first suggested the idea of in-house testing.

3. Scope

The State of Connecticut's current testing hierarchy (those who will be prioritized for testing) for all current testing centers is firstly, admitted patients and then secondly, healthcare providers. While 1st responders may be considered healthcare, family members and others domiciled with responders are likely not. However, due to the significant timeline impact of a first responder return to work and the inability to "control" the testing timeline using conventional processes, the PSCT program will have an expanded spectrum. It will encompass COVID testing for responders, persons domiciled with a responder, or when there is a distinct articulable reason for when testing a source person can directly impact a responder's status or availability to work. Rough estimates suggest that there may be ~240 responders and approximately 720 family members (predicated upon 3 family members per responder), for a total of 960 people who may fall into the population subject to testing under this program.

4. <u>Authority / Permissions / Points of Contact</u>

The PSCT program has several key permissions which allow for the West Hartford Fire Department to perform sample collection. They are as noted below:

a. CT Department of Public Health – Facility Licensing and Investigation Section (FLIS)

In 1988, the US Congress passed the Clinical Laboratory Improvement Amendments (CLIA) which allows for standards to be promulgated for certain laboratory testing to ensure accuracy, reliability and timelines of test results. For the purposes for the PSCT program, the agency responsible for collecting the specimens is required to have a valid "CLIA waiver". A CLIA waiver indicates that the tests which are to be waived from the laboratory requirements are "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result".

On April 2, 2020, Fire Chief Greg Priest verbally communicated with Shelly Olm from FLIS. Ms. Olm confirmed that the West Hartford Fire Department has a valid CLIA Waiver. The original waiver was related to the Fire Department's paramedic program and the use of blood glucometers. Per Ms. Olm, COVID testing is a waived test and can be conducted provided the Department uses personnel properly trained, is done using a written procedure and the FLIS section is to be notified when testing commences. Ms. Olm was consulted and confirms that either use of a point-of-care testing machine or specimen collection for submission to another laboratory was permitted. For the purposes of the requirement of notifying DPH FLIS, this document will be submitted when testing is started.

Also, on April 2, 2020, Chief Priest renewed the CLIA waiver online and exchanged email correspondence with Ms. Olm to verify the renewal and verbal conversation. Evidence is noted in Appendix A (CLIA renewal) and Appendix B (Correspondence with Ms. Olm).

b. West Hartford Fire Department Sponsor Hospital Medical Control & Health District

The West Hartford Fire Department (WHFD) is a certified emergency medical services (EMS) service. As part of the certification requirements, a sponsor hospital medical control physician is required to oversee and dictate the care and protocols to be used by the EMS service. Currently, WHFD enjoys a very productive relationship utilizing Hartford Hospital to provide medical control. The EMS coordinator is David Bailey and the Medical Control Physician is Dr. Charles Johndro. As the nature of a pandemic infectious disease is overseen by local and State health departments, WHFD also has had a significant interaction with the West Hartford/Bloomfield Health District. Director Aimee Krauss has been heavily involved in many decisions regarding the health, safety and quarantine of public safety responders in addition to the public. Several times during the month of April 2020, Fire Chief Greg Priest had verbal conversations with all three individuals who have understood the challenges and reasoning for increasing testing and control over testing. Pre in house testing, Dr. Johndro's assistance was required to obtain tests for WHFD members and family members.

On April 2, 2020, via conference call with the Health District, Dr. Johndro agreed that he would be willing to serve as the "medical control" for the PSCT program as part of his duties as the West Hartford Fire Department medical director. Much like a pre-hospital EMS protocol where standing orders are used, Dr. Johndro would be considered the ordering physician for the test. It is important to note that Dr. Johndro will not be establishing a direct physician relationship with the source individual but the tests are under a standing order. After test results are returned, the expectation is that if the source patient requires direct medical care, it will be secured through other avenues such as a primary care physician or urgent care center. This principle will be enumerated in the consent form to be obtained by the source patient.

Also on April 2, 2020, Director Krauss from the Health District offered her support of the program and noted that there was a value in the control over and accessibility of rapid result tests for public safety members.

c. CT Department of Public Health – Office of Emergency Medical Services (OEMS)

As previously noted, the West Hartford Fire Department (WHFD) is a certified emergency medical services (EMS) service. As such, services fall under specific statues and regulations for pre-hospital EMS. On April 2, 2020, Fire Chief Priest spoke with OEMS Director Rafaella Coler. The basic framework of the PSCT program was presented to Director Coler with the specific question of whether pre-hospital

services can perform this type of testing (either point-of-care or specimen collection). Chief Priest was advised that there was no prohibition on the activity provided the sponsor hospital medical control physician approved. When the conversation with Dr. Johndro was conveyed, Director Coler stated that there would be no regulatory issues with her office. However, it is notable to point out that Director Coler advised that she thought that there were three concerns she had with the PSCT but none that would prohibit it from moving forward. First, the availability of testing "reagent" to perform tests, secondly, the use of PPE needed to conduct the tests in the face of shortages and lastly, she felt that there were sufficient opportunities to obtain testing for "healthcare" personnel through conventional means. While these reservations were considered, the benefit to having the availability of in-house testing still remains critical as the reliability of conventional testing is questionable.

d. The Jackson Laboratory

On Friday April 10, 2020, members of the Town of West Hartford, headed by Mayor Shari Cantor and members of The Jackson Laboratory, headed by President and CEO Edison Liu convened a conference call to discuss the problems facing West Hartford first responders. A framework of the PSCT was presented and discussed, including an outline of all of the permissions that had been secured from Dr. Johndro and the CT Department of Public Health. All parties were excited at the possibility of collaboration to improve testing for responders and as a result, The Jackson Laboratory staff agreed to enter an agreement with West Hartford to initiate the PSCT. The agreement between the Town and The Jackson Laboratory (Clinical Reference Laboratory Terms & Conditions) is attached in Appendix C. This document further outlines the parameters and operations of the PSCT, in compliance with the agreement.

e. Points of Contact for the PSCT:

Agency	Title	Name	Phone	Email
Town of West Hartford	Mayor			
Town of West Hartford	Town Manager			
Town of West Hartford	PIO			
Jackson Lab	President/CEO			
Jackson Lab				
Hartford Medical Control	Medical Control MD			
Hartford Medical Control	EMS Coordinator			
Health District	Acting Director			
West Hartford Police	Chief			
West Hartford Fire	Chief			

5. Selection of Individuals requiring Testing

Especially in the early phases of the PSCT, it will be important to ensure there is proper application. Further, as noted in Section 13 below regarding the volume of tests, the Town must be judicious with the number of tests submitted so as not to exceed the total weekly amount allocated by The Jackson Laboratory. As such, the selection of an individual for testing will require the approval of the West Hartford Chief responsible for the individual (Fire Chief / Police Chief), and Health Director Aimee Krauss or designee. To authorize (order) a test, _________'s protocol is as follows:

- 1. When a situation presents where a responder's work status may be more clearly known or changed, the respective Fire or Police chain of command shall be notified.
- The Chief or designee shall ensure that the test will be given to a responder themselves, someone domiciled with the responder, or confirm there is a distinct articulable reason for testing that impacts a responder's work status.
- 3. The responder or person to be tested must be symptomatic (signs/symptoms consistent with COVID19). Newly post-exposure (72 hours or greater) so that there is a high probability that the test will be reliable. For a currently asymptomatic individual, a determination is made based on the level of close contact exposure with a known COVID positive.
- 4. Provided these criteria are met, and the testing is approved by the Chief, the Chief or designee may contact Director Krauss for concurrence or consultation.
- 5. Provided all criteria are met in the aforementioned items, the test will be considered ordered under Dr. Johndro's medical oversight. Source individuals will be provided the opportunity to speak with Dr. Johndro if they have questions about the testing process that are not enumerated in this document or that cannot be answered through their direct points of contact.

5. Type of Test Selection

In accordance with the Jackson Laboratory's "COVID-19 Sample Acceptance Criteria", noted in Appendix D, there are several means for specimen collection. At the time of document publication, the West Hartford Fire Department utilizes anterior nare (AN) as the primary collection source. Nasopharyngeal (NP) is the secondary collection source. Saliva (sputum) is not currently a validated test collection medium per Jackson Lab. WHFD will collect samples with materials made available from Jackson Lab and will be submitted in accordance with the Sample Acceptance Criteria.

6. Acquisition of Testing Materials/Mediums

The partnership with Jackson Labs allows for the acquisition of sample collection materials. The turnaround time to receiving materials post request is less than 24 hours.

7. Training / Selection of Personnel conducting Specimen Collection

The West Hartford Fire Department will solicit for volunteers from within its paramedic/EMT ranks to be trained in specimen collection. Members will be expected to perform specimen collection while in an on-duty status. Whenever possible, two (2) public safety members will be present for all specimen collection. The first member will be assigned to be in PPE and is the "specimen collector". The second member "monitor" will be at a safe distance from the individual(s) to be tested, in minimal PPE, and is responsible for the administrative and documentation requirements (See Section 9 and 10 below),

monitoring the safety of the process, and assisting with the decontamination of the specimen collector. The Jackson Laboratory does not currently provide training in specimen collection. A train the trainer program was established in partnership with the West Hartford Health District. Currently, eight West Hartford Public Safety personnel are trained in sample collection. Training materials are located in Appendix E of this document.

8. Personal Protective Equipment for Specimen Collection

When testing is authorized and a specimen is to be collected, personnel collecting the specimen will be in a level of PPE that is at or higher than the most current CDC recommendation. Upon completion of the specimen collection and packaging, the collector will be decontaminated and change his/her clothes as necessary for the type of sample being collected. In order to conserve PPE and reduce potential exposures to collectors, individuals selected for testing will be tested in a single area, at one time, with appropriate PPE (mask). An individual receiving a test immediately leaves the testing area without any further interaction post sample collection.

9. Consent of Individuals being Tested

Out of the abundance of caution, the West Hartford Fire Department will produce a basic form where the source individual will consent to the specimen being collected and that the test information will be shared with Public Safety Administrators, the Health District, Medical Control and if applicable, with the responder(s) whom are impacted. The purpose of the consent form is to ensure that the Department is protected from a challenge to HIPAA requirements when information is disseminated. Further, as discussed in Section 3(b), the consent form will clearly enumerate that the medical control physician responsible for oversight of the program and promulgating the protocol for which persons are tested, is not establishing a direct patient-physician relationship. This provides medico-legal coverage to the medical control physician.

The source individual will also be offered and requested to provide consent for biomedical research.

Due to contact concerns during the specimen collection process, the form will be made available online for review prior to testing, and will be read to each person prior to testing. The individual will provide his/her verbal consent and the specimen collector will document the consent.

10. Record-Keeping, Exchange of Information

The West Hartford Fire Department has a HIPAA compliant cloud-based electronic medical records system, ESO Solutions. In order to keep a secure record of the process and test results, when a person is to be tested, the monitor (noted in Section 7 above) will complete an abbreviated electronic health record (EHR). The EHR will be required to have the individuals name and demographic information, reason for test, person(s) authorizing the test, symptoms if any, specimen type taken, and the name of the specimen collector.

At the completion of the specimen collection, the monitor will enter the specimen (sample) information into The Jackson Laboratory's secure web-based laboratory management systems, the Clinical Portal. The monitor will ensure all specimen information is entered directly into the Clinical Portal. After entering into the Clinical Portal, the monitor will note the time/date and delivery information into the ESO as well as any corresponding specimen tracking numbers generated by the Clinical Portal system.

The Reference Laboratory agreement between West Hartford (a HIPAA covered entity) and The Jackson Laboratory, allows HIPAA protected health information (PHI) to be shared between the parties. When the Jackson Laboratory has completed a test and produced a result, it shall be transmitted securely back to the West Hartford Fire Department. The EHR will then be updated with the test result. Notifications and contact tracing shall then be made as outlined in Section 14 below.

11. Location for Specimen Collection

Whenever possible, the specimen shall be collected in an outdoor area and within the Town of West Hartford. In unusual circumstances due to weather, the collection will take place in an open bay garage with ventilation. The area will be secured prior to testing and decontaminated after test completion. The testing locations have been approved by CT DPH FLIS. West Hartford approved testing locations (1) Station 2, 20 Brace Rd; (2) West Hartford Police garage, 103 Raymond Rd.

12. Transport of Specimen, Chain of Custody

After securing the samples, the specimen collector shall follow the protocol enumerated in Section 15 and following the guidance from the training materials in Appendix E. The specimen sample shall be placed into triple packaging, on ice and brought directly to The Jackson Laboratory at 263 Farmington Avenue Farmington, CT. The sample must have been entered into the Clinical Portal prior to drop-off, must be labeled in a manner promulgated by Jackson Lab and must be dropped off following protocols enumerated by The Jackson Laboratory. Refer to Section 15 below and Appendix J, the Jackson Laboratory's Scope of Work document.

13. Volume of Tests

Currently, The Jackson Laboratory has agreed to run up to approximately 20-30 COVID-19 tests a week for the PSCT program. Should the Town desire additional testing, they shall contact The Jackson Laboratory's primary point of contact (Rich Lussier) to determine the availability of more testing. The Town of West Hartford to date has not exceeded 30 tests in a 7-day period.

14. Receipt of Test Results Protocol (Notification Sequence)

When a test result is obtained by the Jackson Laboratory, they will notify the Town's primary points of contact. Information will be transmitted securely, through a secure online fax service. After receipt of results, Chief Priest or designee will contact the individual tested, the Police Chief (if applicable) and Director Krauss so that any immediate actions may be taken. Chief Priest or designee will ensure that the test results are recorded in the individual's EHR within the ESO Solutions Program and that appropriate contact tracing is initiated. The Town will be mindful of privacy and stigma limiting the amount of information disclosed to only those persons who need to know.

15. <u>Approval, Specimen Collection and Testing Procedure (Flow</u> Chart)

- I. Need for Test Presents
- II. Information Submitted to Police/Fire Chain of Command
- III. Department Designee reviews situation and for Criteria in Section 4
- IV. If approved to proceed, contact Health District Designee
- V. If Health District concurs, Fire Chief (or Designee) notified to initiate testing
- VI. Sample Collection Protocol
 - a. Subject to be tested directed to report to a fire station 2 or police garage at designated time, instructed to remain in vehicle
 - b. Admin personnel conducting test notify ERC of test and request incident number. Line personnel are placed last due status to complete testing
 - c. Monitor makes contact with subject (phone preferable); a seamless document requesting testing information must be electronically submitted prior to test.
 - i. Name, DOB, Basic narrative reason for test, who approved it, type of test sample being taken is obtained in seamless document
 - d. Tester obtains specimen collection materials, dons PPE suitable for sample collection (double glove required).
 - e. Tester has open top carry-all container. Container to have sample collection material, x2 plastic sealable, decon wipes, bleach spray and collection cooler
 - f. Tester approaches car collects sample.
 - g. Subject allowed to depart.
 - h. Tester places specimen sample into a plastic bag. Medic then bleaches outside of bag and the carry-all container. Place 1st bag into second bag. 1st set of gloves removed. Rebleach exterior of 2nd bag, place into collection cooler
 - i. Medic returns to monitor drops carry-all off, heads to decon.
 - j. Monitor then enters sample information into Clinical Portal.
 - k. Transportation cooler is placed into transport vehicle.
 - I. When tester is done with Decon, vehicle brings sample to Jackson Labs.
 - m. Tester drops off sample, waits for cooler to be decontaminated and documents sample information into EHR/ESO.
 - n. Personnel return to service.

16. Fees for Testing

As outlined in Appendix J, the Jackson Laboratory's Scope of Work document, the fee for COVID testing is ______. Should antibody or influenza testing component be added, the cost would be communicated to the Town.

17. Public Relations / Media Outreach Protocols

All parties in this partnership agree that consistent, accurate, coordinated and approved messages are paramount. As such, all media inquiries and press releases shall be coordinated between the Town's and The Jackson Laboratory's public information officers (PIO). Written materials, such as this document, will not be released without approval from a PIO. Whenever possible, any releases of a written nature shall be exchanged between the Town and The Jackson Laboratory prior to dissemination.

18. <u>Legal / Regulatory Analysis</u>

The Clinical Reference Laboratory Agreement (Terms & Conditions) has been evaluated for legality by their respective party's legal counsel. To the extent possible, the content of this document will be requested to be reviewed by CT DPH OEMS and FLIS to ensure that all matters of regulatory compliance are in place. Lastly, the Town's Corporation Council, Human Resources and Risk Management will be solicited for input to ensure compliance with Town rules and Worker's Compensation law.

19. Future Expansion of Partnership

The Town and The Jackson Laboratory agree that the PSCT is likely to be very beneficial to the Town and its response force. To that end, additional possibilities for remain present with the most significant being the possibility of leveraging any of The Jackson Laboratory's future capabilities for COVID19 antibody and/or influenza testing.

20. SUMMARY OF CHANGES/UPDATES/LESSONS LEARNED

The following are significant changes, updates or lessons learned since program inception.

- Early on in the pandemic, the executive Chief Officers were assigned and remain assigned into emergency management and ICS systems for the Town in addition to continuing with the normal operations and administration of the Fire Department. Two (2) temporary assignments of line staff into administrative positions were created to address reducing virus spread in the community (Community Support Officer) and to manage reducing virus spread in the public safety departments inclusive of administering the PSCT program (Planning/Recovery Officer). The personnel assigned to these positions have proved invaluable and both directly support and participate in the execution and logistics of the PSCT program
- The transmission of results used to be through a hardline fax machine. We are now using a secure online fax service with multiple recipients. This was a major improvement to allow results to be obtained 24/7. Allows for seamless attachment to PCR for documentation
- The original plan was for all WHFD medics to perform specimen collection. Currently, only a core group of testers is used. The core group consists of several Fire Department paramedics and EMTs, primarily the FD Planning/Recovery Officer and Community Support Officer, as well as several Police Department Officer/EMTs. The police officers were added for police department personnel or related to police duty status. This also resulted in more testing personnel on day shift and a reduced need for off-duty personnel to be called in to perform tests. Lastly, a core manageable testing team is working with a higher degree of consistency and competency with testing procedures.

- The integration of online "seamless documents" or online forms with a prescribed workflow has streamlined testing and provided a foundation for rapid contact tracing. Additionally, while many of the events are very case-specific, the forms have allowed for consistency of process.
- The turnaround time for test results has been very good and is roughly 12-18 hours 90% of the time. The remaining 10% the results arrive in 18-24 hours.
- Preparation, sample collection, delivery and documentation can take up to two hours to complete if testing multiple people.
- The consolidation of one testing medium (anterior nare) has made the process more efficient and less invasive for the test recipient.
- A significant portion of time of the Planning/Recovery Officer who is the primary point of contact for the PSCT program is spent on contact tracing and addressing questions about testing needs/situations.
- With the level of success in the program and upon review of those Town employees considered
 essential, the definition of "public safety member" and/or "responder" has been expanded to
 include members of the Town's Emergency Operations/ Incident Command System staff. This
 added 5 new public safety members, and total potential of 15 people to the program (adjusted
 for family). The addition of this group is being handled by the Fire Department's chain of
 command for test approval.
- Public Works has always been considered a "first responder" but was not originally included in the program. Based upon the effectiveness of the program and with inclement winter weather expected, Public Works employees are likely going to be included as public safety members or responders. Discussions are actively underway to bring the essential Public Works employees into the PSCT program. This will likely add approximately 150 people to the possible population of responders and family eligible for testing for a grand total of approximately 1125. The likely model will involve a primary point of contact at Public Works who will handle test evaluation, authorization and contact tracing for public works employees.

21. <u>Appendices Attached (General Distribution)</u>

- a. West Hartford Fire Department CLIA Waiver Information
- b. Jackson Laboratories Reference Lab Agreement (Draft)
- c. Jackson Laboratories COVID-19 Sample Acceptance Criteria
- d. Sample Consent Forms
- e. Request for Test Seamless Document
- f. Contact Tracing Seamless Document
- g. Policy Directive 20-49 COVID-19 Testing Guidance
- h. COVID-19 Test Flowchart

22. Appendices Redacted / Available

- a. Correspondence with State of Connecticut
- b. Clinical Reference Laboratory Agreement (Terms & Conditions)
- c. The Jackson Laboratory's Scope of Work Document