STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

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Interim Guidance for SARS-CoV-2 Antigen Testing and Reporting in Connecticut – September 29, 2020

"Rapid" antigen testing for SARS-CoV-2 can be helpful and lead to more timely contact tracing and testing when timely turnaround times for molecular reverse transcription polymerase chain reaction (RT-PCR) results are not achievable. Antigen tests can provide point-of-care diagnosis for individuals presenting with possible COVID-19 infection and can be more affordable than RT-PCR tests, however detection of viral antigen is generally less sensitive than nucleic acid detection using RT-PCR.

SARS-CoV-2 antigen tests with Emergency Use Authorization (EUA) from the U.S. Food & Drug Administration (FDA) are becoming increasingly available to clinicians for rapid diagnosis of COVID-19.[1] The Centers for Disease Control and Prevention (CDC) and FDA both provide guidance regarding the use of SARS-CoV-2 diagnostic tests, including antigen tests.[2,3]

This guidance from the Connecticut Department of Public Health (DPH) synthesizes current guidance for the effective use of SARS-CoV-2 antigen tests and outlines reporting requirements. Additional guidance for Abbott BinaxNOW antigen tests is forthcoming.

Summary of Recommendations

- **Prioritize PCR for screening asymptomatic individuals.**
- **Consider using antigen testing for:**
  - **Symptomatic individuals with recent-onset symptoms consistent with COVID-19**
  - **Asymptomatic individuals who undergo serial screening (e.g. nursing home staff/residents)**
  - **Asymptomatic individuals who previously tested positive for SARS-CoV-2 and need asymptomatic screening**
- **Clinicians should be familiar with the performance characteristics of the antigen tests used and follow manufacturer's instructions for specimen collection and handling.**
- **An active CLIA Certificate of Waiver is required before conducting POC antigen testing, and the attached attestation form must be submitted to DPH.FLISLab@ct.gov.**
- **Patients should be provided the Patient Fact Sheet for the EUA test performed. See Reference #1 for Fact Sheets.**
- **Report ALL test results (positive and negative) to DPH. Additional case report must be submitted for ALL positive findings, even if confirmatory RT-PCR result is negative. See Reference #9 for detailed instructions.**

Considerations for SARS-CoV-2 Antigen Testing

Sensitivity data

Test sensitivity generally wanes as time from symptom onset increases. Sensitivity data for antigen tests with FDA EUAs are generated from comparisons with RT-PCR (percent positive agreement with gold standard). These data are from testing specimens collected from patients who presented with symptoms.

Ordering providers can find sensitivity data in the "Clinical Performance" section on the package insert of any antigen test that received FDA EUA. The manufacturer's package insert also specifies when confirmation with a molecular assay (i.e. RT-PCR) should be considered for patient management. Clinical performance and the potential need to pursue confirmatory testing should be considered when discussing antigen testing with patients and making decisions regarding the use of antigen testing.

Sensitivity data may change with further validation of these assays. FDA has a SARS-CoV-2 Reference Panel for comparing sensitivities: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data

Obtaining a Quality Specimen

Most antigen test kits come with nasal or nasopharyngeal swabs, however not all do. Specimen collection instructions provided with each test kit can vary; to achieve optimal consistency and accuracy, follow the manufacturer's instructions for nasal or nasopharyngeal specimen collection and handling. In some cases, observed self-collection may be possible.

Testing Individuals with COVID-19 Symptoms

Anyone with symptoms suggestive of COVID-19 should self-isolate and seek testing. Isolation should continue while awaiting test results (and as applicable, confirmatory test results). See "Counseling Patients to Self-Isolate at the Time of COVID-19 Testing" below.

Antigen tests are best suited for patients presenting with recent-onset symptoms consistent with COVID-19. Ordering providers should review the "intended use" on the package insert provided by the test manufacturer. The package insert will typically specify:

- The antigen test is intended for patients presenting with symptoms[4] consistent with COVID-19, and that it is intended for use within a certain number of days after symptom onset.
- In some situations, negative antigen test results in symptomatic patients may be considered "presumptive negative" and confirmation with a molecular assay (i.e. RT-PCR) should be considered for patient management.

CDC and CT DPH recommend confirming negative antigen test results with an RT-PCR test when the pretest probability is high.

- **Pretest probability (the likelihood of COVID-19) is elevated when the patient is symptomatic or has a known exposure to a person confirmed to have COVID-19; confirmatory testing with RT-PCR is recommended for negative antigen test results in these cases**.
- Confirmatory PCR should be obtained as soon as possible within 48 hours of the initial antigen testing.

Testing Individuals *Without* COVID-19 Symptoms

A highly sensitive test (i.e. RT-PCR) should be considered when screening asymptomatic individuals. If such testing is not feasible, or if turnaround times are prolonged, using antigen tests for screening asymptomatic individuals can be considered even if they are not specifically authorized for this indication (commonly referred to as "off-label" use).[3]

Antigen testing of asymptomatic individuals can be useful for serial screening in congregate care settings such as nursing homes. CDC provides guidance for the use of antigen tests for serial screening in nursing homes.[5]

Testing Individuals *Without* COVID-19 Symptoms (cont'd)

When using antigen testing to screen asymptomatic individuals *without the benefit of serial screening*, the need for confirmatory testing (obtain RT-PCR specimen within 48 hours of initial antigen testing) should be considered. **Clinicians should consider the pretest probability (likelihood of COVID-19) when deciding whether order confirmatory testing.**

- **False positives can occur; consider confirmatory testing for positive results when pretest probability is low.**
  - Low community incidence, no history of exposure, and asymptomatic patient status all lower pretest probability.
  - Some antigen tests can cross-react with proteins on other Human Coronaviruses, including HKU1, which can cause the common cold.
  - When asymptomatic screening produces a positive result and pretest probability is low, the patient should isolate until the result of a confirmatory RT-PCR test is available. In congregate settings, the patient should not cohort with known COVID-positive individuals until the diagnosis is confirmed by RT-PCR.
- **False negatives can occur; consider confirmatory testing for negative results when pretest probability is high.**
  - There is limited data on antigen test sensitivity for asymptomatic individuals.
  - The lower sensitivity of antigen testing compared to RT-PCR might lead to missed asymptomatic infections.
  - RT-PCR should be considered when a negative antigen result if obtained for an asymptomatic person who has a known exposure to someone with confirmed COVID-19 (increases pretest probability).[2] These individuals should quarantine for the full 14-day incubation period regardless of the test result.

Testing Individuals Who Previously Tested Positive for SARS-CoV-2

Individuals who have recovered from COVID-19 can persistently test positive for SARS-CoV-2 by RT-PCR. SARS-CoV-2 RNA shedding can continue in the absence of replication-competent virus in recovered individuals, which is why a test-based strategy (which requires RT-PCR) for lifting of isolation precautions is discouraged.[6]

Retesting is NOT recommended for individuals who previously tested positive for SARS-CoV-2 by RT-PCR (even after a significant exposure to someone with COVID-19) within 3 months/90 days from:

- Symptom onset for the initial COVID-19 infection (if initial infection included symptoms) OR
- The date of the first positive RT-PCR test for SARS-CoV-2 (if initial infection didn't include symptoms)

Asymptomatic recovered individuals with a positive RT-PCR result during this period likely have persistent viral RNA shedding in the absence of replication-competent virus.[6] Patients who experience a recurrence of symptoms during this period after recovery from COVID-19 can be retested for COVID-19 if there are no alternative etiologies for the illness.[7]

Testing *after* the 3 month/90-day period:

CDC recommends retesting recovered individuals for SARS-CoV-2 *after* the 3 month/90-day period if they:

- Develop new symptoms consistent with COVID-19 *after* the 3 month/90-day period
- Are identified as close contacts of a COVID-19 case by contact tracing
- Are in a congregate setting undergoing facility-wide testing for outbreak control

When a recovered individual tests positive for COVID-19 by RT-PCR again, decisions regarding whether this represents a new infection and/or infectiousness should be made on a case-by-case basis. Until we know more about reinfection, clinicians should review all available information – medical history, timing of test results, RT-PCR Ct values, and presence of COVID-19 signs and symptoms.[7] Consider consulting an expert in COVID infections if the data for reinfection is unclear.

Since antigen testing detects viral proteins rather than viral RNA fragments, antigen testing can be considered if testing must be conducted (facility requires pre-procedural screening, for example) for individuals who were previously diagnosed with COVID-19. The utility of SARS-CoV-2 antigen tests for this use has not been evaluated however; more data is needed on the use of antigen tests to screen asymptomatic individuals.

Counseling Patients About Antigen Testing

Given tests with EUA have not undergone the same type of review as an FDA-approved or cleared diagnostic test, **all facilities are mandated by the FDA EUA to provide antigen test fact sheets (available on FDA website, Reference #1) to healthcare providers performing/ordering the test and patients undergoing COVID-19 testing.** Providers should also discuss with patients the reasons for confirmatory testing, as applicable, given the performance characteristics of the antigen test.

Requirements Before Antigen Testing Starts

Healthcare Providers using point-of-care devices under FDA-EUA are required to have an active Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver from CMS.

Facilities with active CLIA Certificate of Waiver:

1. Complete the **attached FDA-EUA attestation form** and return to DPH.FLISLab@ct.gov prior to testing patient samples.
2. Submit a copy of a patient test report OR dummy patient chart OR a narrative as to how the results are being recorded along with the above attestation form.
3. Please also indicate how the test fact sheets for healthcare providers and patients are distributed (via hard copy or electronic link). Fact sheets are available from the manufacturer and on the FDA website (Reference #1)

Facilities with no active CLIA Certificate of Waiver:

1. Complete a CMS 116 Application form and return to DPH.FLISLab@ct.gov. Once entered into the CMS database, DPH will notify the facility of their CLIA number immediately.
2. Follow steps 1 & 2 above (for facilities with active CLIA Certificate of Waiver).

Federal and State Reporting Requirements

Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires "every laboratory that performs or analyzes a test that is intended to detect SARS- CoV-2 or to diagnose a possible case of COVID-19" to report the results from each such test to the Secretary of the Department of Health and Human Services (HHS).[8] Under HHS guidance, locations offering point-of-care testing are considered "laboratories", and reporting to HHS is accomplished by transmitting data to state or local public health departments.

DPH has published guidance for reporting ALL COVID-19 results, both positive and negative, to fulfill both federal and state reporting mandates.[9] Test results should be reported to DPH electronically using either HL7 or flat file methods. These options are described in the reporting guidance. Outpatient settings should refer to the section **"COVID-19 Result Reporting by Point of Care Providers or Other Testing Locations"** in the reporting guidance (Reference #9).

In addition to reporting point of care test results, where applicable, healthcare providers must also submit a COVID-19 Case Report Form for each positive test result they receive for a patient.

- **If a positive antigen result is followed by a negative PCR result, a case report form still needs to be submitted for the positive antigen result.** DPH will receive the negative PCR result through laboratory reporting. These data help public health officials understand the use and impact of antigen testing.
- Providers performing point of care testing can include positive case report information in electronic files as described in the reporting guidance.
- Providers can also submit individual reports for patients with a positive result to a secure online portal at https://dphsubmissions.ct.gov/Covid/InitiateCovidReport.

Counseling Patients to Self-Isolate at Time of COVID-19 Testing

Providers who are eligible to bill CMS for counseling services can use existing evaluation and management (E/M) payment codes for CMS reimbursement for counseling about isolation at the time of testing. Please refer to **CMS' counseling checklist:** https://www.cms.gov/files/document/counseling-checklist.pdf

- Discuss the need for isolation immediately, even before results are available. This means wearing a mask and limiting interactions with others as appropriate.
- Discuss importance of informing immediate household members that they too should be tested for COVID-19. Review locations and people for possible exposures within the past 2 weeks.
- Review of COVID-19 signs and symptoms.
- Encourage them to provide information to a contact tracer if they test positive and are called.
- Discuss services available to them to aid in isolating at home.

Counseling Patients After a Significant Exposure to COVID-19

Anyone, whether symptomatic or not, who has had a significant exposure to someone with COVID-19 should self-quarantine at home for 14 days (maximum incubation period) after their last exposure. A significant community exposure is generally considered as close contact < 6 feet for ≥ 15 minutes, *regardless of mask use*.[10] Risk assessment for healthcare personnel considers PPE use.[11]

Quarantined individuals should stay home, at least 6 feet away from others, and avoid contact with people at higher risk for severe illness as they self-monitor for symptoms.

- If symptoms develop during the 14-day quarantine, the individual should follow home isolation guidance for COVID-19 infection and seek medical care and testing.
- A person who tests negative during their 14-day quarantine period should continue to self-quarantine until the end of their 14-day quarantine period.
- If an individual does not develop symptoms during the 14-day quarantine period, then they may be released from self-quarantine.

References

[1]FDA. Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-antigen

[2]CDC. Interim Guidance for Rapid Antigen Testing for SARS-CoV-2: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

[3]FDA. FAQs on Testing for SARS-CoV-2: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2

[4]CDC. Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html#clinical-presentation

[5]CDC. Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html

[6]CDC. Decision Memo: Duration of Isolation and Precautions for Adults with COVID-19: https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

[7]CDC. Clinical Questions about COVID-19: Patients with Persistent or Recurrent Tests: https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Patients-with-Persistent-or-Recurrent-Positive-Tests

[8]HHS. COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115: https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf

[9]CT DPH. Reporting SARS-CoV-2 (COVID-19) Test Results and Cases: Guidance for Laboratories, Point of Care Providers, and Others: https://portal.ct.gov/-/media/DPH/HAI/COVID19-Test-Reporting_092020V11.pdf

[10]CDC. Public Health Guidance for Community-Related Exposure: https://www.cdc.gov/coronavirus/2019-ncov/php/public-health-recommendations.html

[11] CDC. Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID-19: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html

Additional Guidance from The Association of Public Health Laboratories (APHL): Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing: https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARSCov2-Antigen-Testing-Considerations.pdf

Decision Framework: RT-PCR versus Antigen Testing for SARS-CoV-2

Patient Presentation	**RT-PCR** (Gold Standard, No confirmation necessary)	**Antigen** (May need confirmation: performs best during early acute infection)
Symptomatic (diagnosis)	**Gold standard for diagnosis of COVID-19**	Highly sensitive if used within period of "intended use" per manufacturer's recommendation. Negative results may be "presumptive" and need confirmation, particularly if specimen obtained outside of period of "intended use" per manufacturer's recommendation. **Positive results do not need confirmation.**
Asymptomatic (screening)	**Preferred test for asymptomatic individuals**	Off-label (outside the authorization) use if no clinical suspicion of COVID-19 infection or exposure. Limited data, test performance for asymptomatic cases is unknown. **Confirmatory RT-PCR test recommended if:** • **Presumptive negative result and high pretest probability (i.e. known exposure to someone with COVID-19).** • **Presumptive positive result and low pretest probability (i.e. no exposure or facility outbreak, low community incidence)** **Can be used for serial testing of asymptomatic residents and staff of congregate settings (such as long-term care) without confirming presumptive negatives.** • Confirmatory testing for presumptive positives recommended if no known outbreak/exposure in facility and low community incidence. • Isolate (do not cohort residents with presumptive positive results together with residents positive by RT-PCR) until results are available from confirmatory results.

Decision Framework: COVID-19 Testing for Individuals with Prior RT-PCR confirmed diagnosis of COVID-19

Patient Presentation	**RT-PCR** (Gold Standard, No confirmation necessary)	**Antigen** (May need confirmation: performs best during early acute infection)
Prior RT-PCR confirmed diagnosis of COVID-19	Consider using if reinfection suspected and no other etiologies for illness have been identified. **Positive result may reflect persistent RNA shedding OR new infection.*** **Negative results rule out COVID-19.**	**Consider using if reinfection is suspected, or if the patient needs to be screened for COVID-19 for any reason.**†

*When making decisions about infectiousness following a positive result, clinicians should review all available information – medical history, timing of test results, RT-PCR Ct values, and presence of COVID-19 signs and symptoms.
†Utility of SARS-CoV-2 antigen tests for these purposes has not been evaluated

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HEALTHCARE QUALITY AND SAFETY BRANCH

CLIA CERTIFICATE OF WAIVER LABORATORIES UTILIZING MANUFACTURER ASSAYS GRANTED EMERGENCY USE AUTHORIZATION (EUA) BY THE FDA FOR CORONAVIRUS DISEASE-2019 DURING A PUBLIC HEALTH EMERGENCY

This form must be completed and submitted to the CT Department of Public Health, Healthcare Quality and Safety Branch for all Clinical Laboratory Improvement Amendment (CLIA) certificate of waiver laboratories in Connecticut that utilize any manufacturer assay granted EUA from the FDA to perform COVID-19 testing on clinical specimens during a public health emergency.

Facility: _____

Address: _____

Town: _____, CT Zip _____

Telephone number:_____

CLIA #_____

Laboratory Director Name: _____

Testing Platform: _____

Kit Name: _____

Sensitivity of the test: _____

Estimated Test Volume: _____

Days & times testing performed: _____

Testing population (i.e. Inpatient, Outpatient, Healthcare Workers etc.): _____

Turn around Time for testing: _____

Testing capacity:_____

Patient testing start date: _____

Phone: (860) 509-7400 • Fax: (860) 509-7543
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

REPORTING:

1. Please submit a sample test report/dummy patient chart/a narrative as to how the results are being recorded along with this form.

2. SARS-CoV-2, the virus that causes COVID-19 is a reportable laboratory finding. Refer to the Public Health Commissioner's correspondence titled 'Change to the List of Reportable Laboratory Findings'. https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/Facility-Licensing--Investigations/Blast-Faxes/Change-to-the-List-of-Reportable-Laboratory-Findings.pdf?la=en

The Laboratory shall make provisions to maintain appropriate safety and infection control measures at all times.

The undersigned Laboratory Director or designee, duly authorized, responsible for the services performed in the Laboratory, attests that the Laboratory has sufficient staff, equipment, and provisions will be provided to ensure the health and safety needs of the laboratory according to the federal CLIA regulations.

This Attestation shall remain in effect until the Laboratory no longer requires this service or such use by the Laboratory is revoked by the Department upon a finding that the health, safety, or welfare of any staff or patient has been jeopardized.

The parties hereto have caused this Attestation to be executed by their respective officers and officials and will be effective as of the later of the two dates noted below

Date: _____ By: _____

Laboratory Representative

Date: _____ By: _____

Facility Licensing & Investigations Section, Laboratory Section

Healthcare Quality and Safety Branch

Please return this form along with the documentation to: DPH.FLISLab@ct.gov

8/19/20