Frequently Asked Questions:  
Public Health Laboratory Response to COVID-19  
[Updated March 27, 2020]

Specimen Collection and Handling

Q: What are the acceptable specimen types for the CDC 2019-nCoV assay?
A: For initial diagnostic testing for coronavirus disease (COVID-19), CDC recommends collecting and testing an upper respiratory specimen for SARS-CoV-2. Nasopharyngeal (NP) specimens are the preferred choice for swab-based testing. When a NP swab is not possible, the following are acceptable alternatives:

- Oropharyngeal specimens collected by a healthcare professional,
- Nasal mid-turbinate swabs collected by a healthcare professional or by onsite self-collection using a flocked tapered swab, or
- Anterior nares specimens collected by a healthcare professional or by onsite self-collection using a round foam swab.

CDC also recommends testing lower respiratory tract specimens, if available. For patients who develop a productive cough, sputum should be collected and tested for SARS-CoV-2. The induction of sputum is not recommended. For patients for whom it is clinically indicated (e.g., those receiving invasive mechanical ventilation), a lower respiratory tract aspirate or bronchoalveolar lavage sample should be collected and tested as a lower respiratory tract specimen.

See CDC’s Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for COVID-19 and Biosafety FAQs for handling and processing specimens submitted for SARS-CoV-2 testing.

Q: If a nasopharyngeal (NP) swab cannot be collected, is there a preference among alternative specimens?
A: Oropharyngeal, anterior nares or nasal mid-turbinate swabs are all acceptable alternatives to NP swabs. These perform comparatively, though not as well, as NP swabs. Of note, sputum can have a higher viral load than other sampling sites when patients have a productive cough and is also recommended for testing, if available.

Q: Does CDC have additional specimen processing guidance for sputum?
A: Yes, please see Processing of Sputum for Nucleic Acid Extraction.

Q: Is it acceptable to use Aptima unisex collection kits or other specific kinds of swabs?
A: CDC has not addressed the suitability of specific swab brands, but has specified that acceptable swabs should have synthetic fibers and plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing. If the swab you are considering meets those characteristics, it is acceptable to use.

Q: Is saline an acceptable transport media for specimens submitted for SARS-CoV-2 testing? At what concentration?
A: Yes, saline is an acceptable alternative transport medium for all specimen types. CDC uses a concentration of 0.85% saline, but either 0.9% or 0.85% is acceptable.
Q: Regarding the swab and viral transport media alternatives suggested by FDA; are individual laboratories required to establish performance of chosen alternatives with the assay in use prior to implementing usage of the alternative media?

A: In instances where the FDA has indicated that certain alternate collection devices and specimen transport media could be used, the CLIA laboratory director will need to decide if subsequent validation studies are needed before tests are performed. Laboratory surveyors should review the CLIA Laboratory Guidance During COVID-19 memorandum issued by the US Centers for Medicare and Medicaid Services (CMS). Note that CDC has evaluated the performance the CDC 2019-nCoV rRT-PCR Dx Panel with saline as a transport media.

**Specimen Shipping**

Q: What are the recommended storage and shipping conditions?

A: Store specimens at 2-8°C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70°C or below.

Specimens must be packaged, shipped and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations. Ship specimens overnight under the following conditions:

- For specimens stored at 2-8°C: ship on an ice pack.
- For specimens frozen at -70°C: ship on dry ice.

Additional useful and detailed information on packing, shipping, and transporting specimens can be found at Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with COVID-19.

Q: Should presumptive positive specimens from the 2019-nCoV EUA test be shipped to CDC as Category A or Category B substance?

A: Pack and ship suspected or confirmed SARS-CoV-2 patient specimens, cultures or isolates as UN 3373 Biological Substance, Category B, in accordance with the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations (DGR):

1. A leakproof primary container.
2. A leakproof, watertight secondary packaging with absorbent material.
3. A rigid outer packaging to protect the specimens during shipment.

For additional information, refer to the following:

- IATA DGR Packaging Instruction 650
- CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with COVID-19
- WHO Laboratory Biosafety Guidance Related to 2019-nCoV

**CDC 2019-nCoV rRT-PCR Dx Panel**

Q: What is the sensitivity and specificity of the CDC 2019-nCoV rRT-PCR Dx Panel?

A: The assay’s instructions for use detail the panel’s clinical evaluation data and performance in the Performance Characteristics section beginning on page 38 of the document.

Q: Does CDC have any guidance on pooled testing?

A: CDC has not evaluated pooled specimen testing and suggests using caution when considering pooling specimens. There is an inherent dilution factor that occurs with this method. At least one public health laboratory has successfully implemented pooling and has notified FDA that they have done so.
Q: Our laboratory has seen aberrant activity in both N1 and N2 targets, leading to inconclusive and invalid test results. When the test is repeated without re-extraction, the result is negative; does CDC have any guidance on how to proceed when a sample goes from a weak positive to negative upon repeat testing?

A: Repeating is a good first step, particularly for invalid results. However, CDC expects to see a certain number of inconclusive results, particularly when samples have a low viral load; the interpretation of this result is one that the laboratory will have to make. A negative result does not preclude infection and CDC has put out additional guidance on time-based isolation without repeat testing in order to conserve resources. Of note, in cases where the patient has a productive cough, sputum can have higher viral load than other sampling sites, so CDC recommends collecting sputum for further testing. Please continue to report testing issues to respvirus@cdc.gov.

Postmortem Specimens

Q: Does CDC have guidance on postmortem specimens?

A: Yes, please see Collection and Submission of Postmortem Specimens from Deceased Persons with Known or Suspected COVID-19, March 2020 (Interim Guidance)

Q: How should lung tissue from autopsies be submitted to CDC?

A: CDC’s Infectious Diseases Pathology Branch (IDPB) can receive fixed autopsy tissue specimens from known or suspected COVID-19 cases. IDPB will perform histopathologic evaluation, testing for COVID-19 and other respiratory viral pathogens (e.g., influenza), and bacterial or other infections as indicated. Prior notification and CDC approval is required. You can find full instructions in Collection and Submission of Postmortem Specimens from Deceased Persons with Known or Suspected COVID-19, March 2020 (Interim Guidance).

Serial Testing

Q: Does CDC have any guidance on serial sampling or test-of-cure?

A: On March 24, 2020 CDC released updated guidance on testing priorities as well as time-based isolation strategies that may allow laboratories to avoid serial sampling and conserve reagents. The new guidance provides test-based and non-test-based strategies for reducing or removing transmission-based precautions used with patients with COVID-19.

Serology

Q: What serology tests have been granted emergency use authorization (EUA)?

A: FDA has not yet granted EUA of a serologic assay but does not object to the use of serology tests with some caveats. Below is FDA’s guidance on serology tests from their FAQ on Diagnostic Testing for SARS-CoV-2:

The FDA does not intend to object to the development and distribution by commercial manufacturers, or development and use by laboratories, of serology tests to identify antibodies to SARS-CoV-2, where the test has been validated, notification is provided to FDA and information along the lines of the following is included in the test reports:

- This test has not been reviewed by the FDA.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43 or 229E.
More information, including a list of manufacturers that have notified FDA that they have validated and are offering serology tests, who will not be pursuing EUAs, is available in the FDA FAQs on Diagnostic Testing for SARS-CoV-2.

Q: Serology tests have not yet been categorized by FDA, and CLIA has said uncategorized tests should be performed by high complexity laboratories. Does their guidance from FDA on which laboratories are qualified to perform these tests include those that are marketed as point-of-care (POC)?
A: FDA guidance says the serology policy applies to tests for use in labs or by healthcare workers at POC, but it does not address CLIA categorization. CMS considers anything uncategorized to be high-complexity, so—until FDA categorizes serology tests—all COVID-19 testing needs to be performed in a high-complexity laboratory.

Tests Available from Commercial Manufacturers
Q: I have been contacted by a manufacturer who claims to have a test that has been “approved” by FDA. How can I confirm their claim?
A: A list of approved molecular tests can be found on FDA’s EUA website. FDA has not yet granted an EUA for a serology test, but a list of manufacturers that have notified FDA that they have validated and are offering serology tests, who will not be pursuing EUAs, is available at FDA FAQs on Diagnostic Testing for SARS-CoV-2.

Testing in Clinical and Commercial Laboratories
Q: Is a CLIA certificate required to perform SARS-CoV-2 testing even in jurisdictions where governors may have signed executive orders that state otherwise?
A: According to CMS, laboratories need a CLIA certificate to perform COVID-19 testing. Under CLIA, laboratories are prohibited from testing human specimens for the purpose of diagnosis, prevention, treatment or health assessment without a valid CLIA certificate. CMS has implemented an expedited application process for those laboratories that are interested in becoming CLIA-certified to participate in the response.

Read CMS’s memorandum to laboratory surveyors for more information and guidance regarding the COVID-19 public health emergency.

Q: Do public health laboratories need to confirm presumptive-positive SARS-CoV-2 test results for clinical laboratories?
A: No. FDA has determined that after the first five positive and first five negative test results are confirmed, all positives test results thereafter are considered “positive” and do not require confirmation.

Q: What should public health laboratories do if they perform confirmatory testing on the first five positive and first five negative test results for a clinical laboratory and there are discrepant results?
A: Per FDA guidance, “If any of these results cannot be confirmed, the laboratory should notify FDA at CDRH-EUA-Templates@FDA.HHS.gov, and take other appropriate actions such as terminating testing patient specimens, and issuing a corrected test report that indicates the prior test result may not be valid.”

Public Health Pricing
Q: Is there public health pricing available for laboratories interested in buying equipment for testing?
A: Yes, please see APHL’s Public Health Pricing List for more information. This website also includes service agreement pricing and consumables for some vendors.

Contact Information
Q: Where can I discuss my testing questions or issues with other public health labs?
A: APHL maintains a Microbiology Discussion CoLABorate community exclusively for public health laboratorians. You may request to join by emailing APHL at eoc@aphl.org.

Q: Who can I contact with questions?
A: The following can all be contacted with questions:

- CDC Emergency Operations Center (EOC) (for shipment coordination): 770.488.7100
- CDC Laboratory Team (for technical questions): respvirus@cdc.gov
- International Reagent Resource (IRR): call 866.951.2822 or visit the IRR Contact Us webpage
- APHL EOC: email eoc@aphl.org
- APHL Informatics: email informatics.support@aphl.org