Frequently Asked Questions about Laboratory Testing and COVID-19

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For All Laboratories: Accessing Laboratory Testing

How do clinicians get access to SARS-CoV-2 viral testing?

- Clinicians can access laboratory tests for SARS-CoV-2, the virus that causes COVID-19, through clinical laboratories performing tests authorized or intended to be authorized by the U.S. Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA). Clinicians should consult with the laboratories that routinely perform their diagnostic services to see how best to access SARS-CoV-2 testing.
- Clinicians also can access viral testing through their state public health departments. The Association of Public Health Laboratories (APHL) provides a list of available public health laboratory testing locations.
- For a list of COVID-19 EUAs, see FDA's COVID-19 Emergency Use Authorizations for Medical Devices .

Under what circumstances should laboratories use either a SARS-CoV-2 viral or serology (antibody) test that has received EUA from FDA?

FDA has authorized EUAs for both viral and antibody tests for COVID-19. Viral (nucleic acid and antigen) tests are used to diagnose the presence of SARS-CoV-2 infections. In contrast, antibody tests can detect IgG, IgA, and IgM antibodies from an immune response to SARS-CoV-2.

Whenever possible, laboratories should rely on viral tests to diagnose the presence of SARS-CoV-2 infections. However, a negative result from viral testing does not rule out COVID-19.

Most of the PCR-based tests that use two or more targets are likely to have high specificity (few false positives). However, there is some variation in the stated sensitivity of the different assays, and sensitivity is highly dependent on the stage of the disease. For this reason, negative results should always be interpreted in the context of the exposure history and symptoms of the patient.

Results from antibody testing should not be used to diagnose or exclude SARS-CoV-2 infections or to inform infection status. Negative results from antibody testing do not rule out SARS-CoV-2 infections, particularly for those individuals who have been exposed to the virus and are still within the estimated incubation period. Until the performance characteristics of antibody tests have been evaluated, it is possible that positive results from such testing may be due to past or present infections with a coronavirus other than SARS-CoV-2.

If a laboratory initially uses antibody testing for diagnostic purposes, follow-up testing using a viral test should be performed.

Read: Important Information on the Use of Serological (Antibody) Tests for COVID-19: FDA Letter to Healthcare Providers

More: FDA EUA Authorized Serology Test Performance

Where do laboratories get access to reagents and materials to perform viral testing for SARS-CoV-2?

Public health laboratories can access collection materials for SARS-CoV-2 testing, including swabs and transport media, through the International Reagent Resource (IRR) . The IRR supports state and local public health laboratories, as well as other qualified laboratories participating in public health surveillance and studies, by providing reagents, tools, and information for studying SARS-CoV-2 and other pathogens.

Through IRR, CDC also provides the reagents that public health laboratories use to detect SARS-CoV-2 virus in respiratory specimens. One test for SARS-CoV-2 detection is a CDC-developed real-time reverse transcription polymerase chain reaction (RT-PCR) test that received an EUA from FDA on February 4, 2020, to detect the virus in upper and lower respiratory specimens. IRR also provides several additional commercially produced assays that have received an EUA from FDA to detect SARS-CoV-2 viral RNA in respiratory samples.

Clinical and commercial laboratories conducting SARS-CoV-2 viral testing can acquire test reagents from commercial reagent manufacturers that have received EUA from FDA. Genomic RNA material for validation purposes can be obtained from BEI Resources as indicated below.

Can laboratories use specimen collection devices other than those listed in the manufacturer's instructions or EUA (e.g., swabs) for SARS-CoV-2 testing?

According to FDA, when one entity establishes equivalent performance between parallel testing of the same specimens with the new and original components (including viral transport media [VTM]), and FDA's review of the validation data indicates that it could be applicable to modifications of other tests with an authorized EUA, FDA will post this information on its website so that other laboratories can refer to the validation for their testing. Then, other laboratories do not need to conduct their own bridging study for the same modification. For additional information regarding FDA's policy for modification, see FDA's frequently asked questions website.

Where can I find additional CDC guidance about laboratory testing?

CDC has published the following interim guidelines and updates them regularly:

- Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)
- Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19)
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
- Laboratory Biosafety and COVID-19: Questions and Answers
- CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use

I can't find viral transport media (VTM) for SARS-CoV-2 testing. What are my options?

Public health laboratories can order VTM through IRR, as noted above.

Clinical testing laboratories should acquire VTM from commercial sources.

Public health and clinical laboratories can also create their own VTM if they are unable to order it. In response to VTM shortages, CDC has posted a standard operating procedure to create VTM for laboratories. Saline is also an acceptable transport media for some COVID-19 viral assays, including the CDC EUA. Check the Instructions for Use with the EUA Assay to see which transport media is acceptable.

My facility would like to begin SARS-CoV-2 testing. Do we need a Clinical Laboratory Improvement Amendments (CLIA) certificate? Can my facility be granted a waiver from the CLIA certification requirements so that I can begin testing immediately?

Before conducting SARS-CoV-2 viral testing, a laboratory must be CLIA-certified and meet applicable regulatory requirements. The Centers for Medicare and Medicaid Services (CMS) does not have the authority to grant waivers of exceptions that are not established in a statute or regulation. For additional information, please refer to the FAQs on the CMS website: CMS Coronavirus Information .

What is the CLIA test complexity categorization of SARS-CoV-2 tests that do not have an EUA?

Tests for SARS-CoV-2 that are offered prior to or without an EUA have not been reviewed by FDA, are not FDA-authorized, and have not received a CLIA categorization. Thus, those tests are considered high complexity by default until they receive an EUA or other FDA review that indicates they may be performed as moderate complexity or waived tests. For more information, visit FDA COVID-19 Resources, and navigate to the section titled "General FAQs."

When FDA authorizes emergency use for a SARS-CoV-2 point-of-care test, can that test be used in CLIA certificate-of-waiver facilities?

When the FDA grants an EUA for a point-of-care test, that test is deemed to be CLIA-waived. For the duration of the national emergency declaration for COVID-19, such tests can be performed in any CLIA-certified patient care setting with a certificate of waiver.

How do I apply for a CLIA certificate so that my testing facility can perform SARS-CoV-2 testing?

The federal CLIA program contracts with states to carry out certain oversight and recording functions of the CLIA program. The state in which the laboratory is located processes applications for CLIA certificates. After the laboratory has identified a qualified and certified laboratory director and has provided all required information on the CMS-116 application, a CLIA number will be assigned and the laboratory can begin testing if applicable CLIA requirements have been met. For additional information, please refer to the FAQs on the CMS website: CMS Coronavirus Information.

Are pathologists able to sign out cases remotely during the COVID-19 public health emergency?

CMS has indicated that it will allow laboratories to use temporary testing sites for remote review and reporting of laboratory data, slides, and images if specific criteria are met. Please refer to this CMS Memorandum for additional information.

Can a pooling strategy be used to expand nucleic acid testing for SARS-CoV-2? –

In areas with low COVID-19 prevalence, a two-stage specimen pooling approach can help preserve testing reagents and resources. In the first stage, several patients' specimens are combined before extraction, and then tested all at once. If the test comes back negative, then all of those patients can be cleared with one test. If the test comes back positive, then all of those specimens need to be extracted and re-tested individually.

The lower the prevalence of the disease, the larger the optimal pool size can be. A recent study from the Nebraska Public Health Laboratory found that polymerase chain reaction (PCR) tests for SARS-CoV-2 reliably return a positive result when one positive sample is mixed with four negatives. Researchers in Germany and Israel have had similar results.

A pooling strategy is **not efficient** when the prevalence of COVID-19 is high. People with symptoms and people who have been exposed to someone with a confirmed SARS-CoV-2 infection should still be tested individually.

Before using a pooling strategy, the laboratory must have the proper regulatory approvals. If the manufacturer's guidelines and the emergency use authorization (EUA) for that SARS-CoV-2 test do not stipulate pooling, laboratories that use authorized nucleic acid devices can still bridge to alternative components, including extraction methods, PCR instruments, software versions, etc., under Section IV. A. 4. of FDA's Policy for COVID-19 Tests During the Public Health Emergency . These component changes can be achieved through evaluation and verification of the performance of the component with the test, without a new EUA or an amendment to the original EUA. Additional detail and suggested studies are discussed in FDA's policy. The process used for such changes must also comply with Clinical Laboratory Improvement Amendments (CLIA) guidelines.

For All Laboratories: Test Developers

Where do test developers get the genomic RNA needed to validate test performance for FDA?

- Currently, genomic RNA material can be used for validation purposes in biosafety level 2 laboratories (BSL-2). Genomic RNA material is available through BEI Resources . Registration with BEI Resources is required to request SARS-CoV-2 materials. BEI Resources is prioritizing and fast-tracking all SARS-CoV-2 registrations with a 12- to 72-hour turnaround time for all SARS-CoV-2-related registrations. Please contact BEI Resources at contact@beiresources.org or 1-800 359-7370 for questions.
- Developers are required to sign a material transfer agreement prior to the release of materials.
- All BEI Resources reagents are provided worldwide. There is no cost for the reagents themselves. However, shipping and handling charges may apply.
- Commercial sources also may have this material.
- ***For Public Health Laboratories:*** If a kit to detect the virus (SAR-CoV-2) is needed, contact the International Reagent Resource

What is NIH's BEI Resources Repository?

BEI Resources Repository was established by the National Institute of Allergy and Infectious Diseases at the National Institutes of Health to provide reagents, tools, and information for studying Category A, B, and C priority pathogens, emerging infectious disease agents, non-pathogenic microbes, and other microbiological materials of relevance to the research community including diagnostic developers. Centralizing these functions within BEI Resources facilitates access to these materials by the scientific community and ensures quality control of the reagents.

My facility created a laboratory-developed test (LDT) to detect SARS-CoV-2. We need to have the first five positive and negative specimens confirmed. Can we send these specimens to CDC?

Laboratories using an LDT to detect SARS-CoV-2 should confer with their state public health laboratory for assistance. If the state public health laboratory cannot assist, contact respvirus@cdc.gov.

For All Laboratories: Serology

Does CDC accept specimens for antibody testing?

CDC is currently performing antibody surveys to understand how COVID-19 has spread in the U.S. population. CDC is not using its antibody tests for diagnostic purposes, and thus is not accepting antibody test requests intended for COVID-19 patient diagnosis.

Will CDC submit its antibody test for an EUA?

Not at this time. CDC is using its antibody test as part of a multi-agency study to evaluate current commercially marketed antibody tests for specificity and sensitivity and to help determine how results from antibody tests could support policymaking. CDC will share information publicly on the recommended use of antibody testing as soon as enough data becomes available.

Should I test for IgG, IgM, or total immunoglobulin?

The decision to test for IgG, IgM, or total immunoglobulin, which could also include IgA, depends on the purpose for testing. Testing for total immunoglobulin may increase sensitivity for identifying people who have been recently infected. Testing for IgG may be a better marker of durable immunity to SARS-CoV-2. However, we need additional data on the maturation of the immune response to SARS-CoV-2 to make evidence-based recommendations for all testing scenarios. Scientists from CDC and elsewhere are investigating how SARS-CoV-2 antibody responses develop over time.

For Public Health Laboratories: Ordering Supplies

What Is CDC's International Reagent Resource (IRR)?

The International Reagent Resource (IRR) was established by CDC more than 10 years ago. It provides registered users with reagents, tools, and information for studying and detecting influenza virus and other pathogens, including SARS-CoV-2. IRR is primarily a resource used for procuring pathogen test components and assembling, qualifying, and distributing these kits for use in CDC-directed public health activities. This resource supports detection and characterization of pathogens, which will aid in informing interventions. By centralizing these functions within IRR, access to and use of these materials in the scientific and public health community is monitored and quality control of the reagents is assured.

To support health departments during the COVID-19 pandemic, IRR has expanded to provide more products needed for viral testing, including numerous commercially produced Emergency Use Authorization (EUA) assays. IRR is managed under a CDC contract by American Type Culture Collection (ATCC).

What supplies are being distributed by IRR for COVID-19 testing?

The expanded catalog of COVID-19 diagnostic supplies includes:

- **Extraction kits**, to isolate the viral genetic material (RNA)
- **Test kits**, to determine the presence of SARS-CoV-2
  Click here for more information about CDC's test kits
- **DISCONTINUED: Sample collection kits**, to swab via the nasopharynx, suggest nose, and/or throat **(See below to learn more about the process for ordering swabs.)**

Where can I find a complete product list of items for SARS-CoV-2 testing?

A comprehensive list of all viral testing supplies available through IRR is provided on the IRR website. New reagents may be added to the IRR catalog as the emergency response progresses.

What is the new process for swab ordering?

Starting April 30, 2020, FEMA is assuming responsibility for the production and distribution of LR-1, Flock Swabs. States can reach out to their federal testing contact. The federal government will work with states who are on pace to exceed their testing goals for the month to meet increased testing demand. Learn more here.

For Clinical Laboratories: Ordering Supplies

Can I register my lab or hospital with IRR?

CDC limits IRR registration and SARS-CoV-2 diagnostic reagent distribution to U.S. state and local public health laboratories validated to perform SARS-CoV-2 viral testing. During the SARS-CoV-2 pandemic, CDC will defer the decision to authorize new laboratories to the corresponding state public health laboratory.

How do I obtain reagents for the CDC EUA real-time RT-PCR assay for SARS-CoV-2?

Clinical laboratories can purchase reagents for the CDC EUA real-time RT-PCR primers and probes from Integrated DNA Technologies (IDT) or Biosearch Technologies. CDC has posted a list of approved reagents and acceptable lots on the CDC COVID-19 website. Clinical laboratories also can purchase commercially developed viral tests with an EUA from the manufacturer.

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