Centers for Disease Control and Prevention

Coronavirus Disease 2019 (COVID-19)

COVID-19 Testing and Reporting by Laboratories: Q & A

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For All Laboratories: Accessing Laboratory Testing

How do clinicians get access to SARS-CoV-2 diagnostic 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 diagnostic 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 molecular or serological test that has received EUA from FDA?

FDA has authorized EUAs for both molecular and serological tests for COVID-19. Molecular tests are used to diagnose the presence of SARS-CoV-2 infections. In contrast, serological tests can detect IgG, IgA, and IgM antibodies from an immune response to SARS-CoV-2.

Whenever possible, laboratories should rely on molecular tests to diagnose the presence of SARS-CoV-2 infections. However, a negative result from molecular 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 serology testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infections or to inform infection status. Negative results from serology 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 serologic 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 serological testing for diagnostic purposes, follow-up testing using a molecular diagnostic test should be performed.

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

Where do laboratories get access to reagents and materials to perform diagnostic 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 diagnostic 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 diagnostic 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 diagnostic 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.

For All Laboratories: Data and Reporting

Why is collecting SARS-CoV-2 laboratory testing data important?

The public health response to COVID-19 depends on having a comprehensive, real-time, county-level view of COVID-19 laboratory test orders and results. These data will contribute to understanding disease incidence as well as testing coverage. On April 5, 2020, the Council for State and Territorial Epidemiologists issued an interim position statement that created a standardized case definition and made COVID-19 a nationally notifiable condition. In addition, laboratory testing data can help identify laboratory supply-chain issues for reagents, personal protective equipment, and other material.

Does CDC require all laboratories to report test results directly to CDC?

No. CDC is working with state health departments to collect SARS-CoV-2 laboratory testing data that they already receive from most clinical laboratories. Data will be collected from state health departments in two phases: Data will be aggregated by county or ZIP code, then states will send de-identified test-level data using electronic HL7 reporting or CSV files. CDC also receives SARS-CoV-2 testing data directly from state and local public health laboratories, a few large commercial laboratories, and its own laboratories. For assistance with reporting SARS-CoV-2 testing results, please send an email to DLSinquiries@cdc.gov.

Note: State public health laboratories and select large commercial laboratories that currently report directly to CDC should continue sending that data.

How is the laboratory test reporting to state health departments different than the collection of laboratory testing data by the White House Task Force?

The White House Task Force is currently collecting aggregate data from hospitals for COVID-19 testing conducted at hospital laboratories. Read: HHS Letter to Hospital Administrators

Who is authorized to receive laboratory testing data?

According to the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, the Secretary of Health and Human Services is authorized to receive SARS-CoV-2 laboratory testing data. CDC is one of several agencies of the U.S. Department of Health and Human Services (HHS). As a result, both HHS and CDC have requested testing data from laboratories. These data will help the public health response understand the number of tests ordered and performed, results of each test, and the percent positive.

Should I report all SARS-CoV-2 test results using standard terminology (i.e., LOINC and SNOMED Clinical Terms)?

Yes. All laboratories should always use LOINC and SNOMED Clinical Terms (CT) standards, when available, to accurately report their testing for infection with the SARS-CoV-2 virus. Standard use of these laboratory codes ensures that the same type of test is represented uniformly across the United States.

For laboratory tests, LOINC codes should be used to represent the "question" a diagnostic test asks of a specimen (e.g., does this specimen have SARS-CoV-2 RNA?), and SNOMED-CT codes should be used to represent the diagnostic "answer" (e.g., what was detected?). More background on these terminology standards can be found here:

- LOINC Term Basics
- SNOMED CT Basics

A list of currently available LOINC codes for the available SARS-CoV-2 tests can be found on SARS-Coronavirus -2 LOINC codes.

Note: CDC encourages test developers and laboratories that use SARS-CoV-2 tests to work together to obtain appropriate and interoperable LOINC and SNOMED-CT codes for reporting purposes.

How should LOINC codes be requested for SARS-CoV-2 laboratory testing?

Whenever possible, laboratories should use standard codes that already exist. Before requesting a new code, search the list of currently available LOINC codes for SARS-CoV-2 tests.

If a LOINC test code cannot be identified whose attributes appropriately match the test for which coding is needed, new terms can be submitted, and a new code requested through the LOINC website.

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 serology testing?

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

Will CDC submit its serology test for an EUA?

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

Should I test for IgG or IgM?

We are currently recommending total Immunoglobin, which would include both IgG and IgM.

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 to provide registered users with reagents, tools, and information for studying and detecting Influenza and other pathogens, including the SARS-CoV-2 virus. IRR has worked to acquire, authenticate, and produce reagents that scientists need to carry out CDC-directed research and develop improved diagnostic tests, vaccines, and detection methods. 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 many products needed for diagnostic testing, including swabs to collect specimens, numerous commercially produced EUA assays, and other materials. The International Reagent Resource is managed under a CDC contract by American Type Culture Collection (ATCC).

What supplies is IRR distributing for SARS-CoV-2 testing?

The catalog of COVID-19 diagnostic supplies includes:

- **Sample collection kits**, to swab the nasopharynx, nose, and throat
- **Extraction kits**, to isolate the viral genetic material (RNA)
- **Test kits**, to determine the presence of SARS-CoV-2

- **Ancillary supplies** required to perform certain commercial tests

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

A comprehensive list of all diagnostic 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.

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 diagnostic 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 diagnostic tests with an EUA from the manufacturer.

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