Coronavirus Disease 2019 (COVID-19)

Frequently Asked Questions about Coronavirus (COVID-19) for Laboratories (Serology)

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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 .

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

Public health laboratories can access test kits and extraction materials for SARS-CoV-2 testing 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.

CDC's real-time reverse transcription polymerase chain reaction (RT-PCR) test to detect SARS-CoV-2 in upper and lower respiratory specimens received an Emergency Use Authorization (EUA) from FDA on February 4, 2020, and is distributed by IRR. CDC's new multiplex assay, which detects influenza A, influenza B, and SARS-CoV-2 simultaneously, received an EUA from FDA on July 2, 2020, and is also being distributed through IRR. 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. Commercial labs can get reagents for CDC's 2019-nCoV Real-Time RT-PCR from qualified sources listed in the instructions for use. A list of commercially available reagents for use with the multiplex assay is not currently available. However, CDC has shared the primers and probes sequences, so other laboratories and companies may manufacture their own reagents. Genomic RNA material for validation purposes can be obtained from BEI Resources as indicated below (in Test Developers FAQs).

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.

I can't find swabs or media for SARS-CoV-2 testing. What are my options?

The US Department of Health and Human Services (HHS) is directly managing allocation of swabs and media, including viral transport medium (VTM), based on state and territory testing plans that were submitted in response to the Coronavirus Aid, Relief, and Economic Security (CARES) Act requirements. Allocations were predetermined to maximize state and territory testing using a data-driven algorithm based on population, high incidence areas, and COVID-19 Task Force's directives. Currently, HHS is distributing the following swabs: nasopharyngeal (NP), nasal, foam, and poly swabs. HHS is distributing the following media: saline, phosphate buffered saline solution (PBS), and VTM. For specific swab or medium requests, delivery site changes, or other related requests, contact COVID19TestSupplies@hhs.gov.

Public health and clinical laboratories can also produce their own VTM if it is unavailable for purchase. In response to VTM shortages, CDC posted a standard operating procedure for the preparation of VTM. Saline is also an acceptable transport medium for some COVID-19 viral assays, including the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Check the Instructions for Use to see which transport medium is acceptable.

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.

I cannot obtain the materials I need to perform CDC's 2019-nCoV Real-Time RT-PCR Diagnostic Panel test. What should I do?

On June 12, 2020, the U.S. Food and Drug Administration approved an amendment to this test's Emergency Use Authorization to allow state public health laboratories and others the flexibility to use the following alternatives:

1. A new authorized extraction method performed with the Roche MagNA Pure 24.
2. Additional extraction reagent options with the already-authorized extraction instruments from Roche and QIAGEN.
3. Heat treatment to replace the extraction method. However, heat treatment is recommended only if insufficient extraction reagents are available to extract every upper respiratory clinical specimen received, since this method could potentially reduce test sensitivity. Please note: Laboratories using heat treatment will still need extraction reagents on hand to aid in resolution of any inconclusive or invalid test results obtained for heat-treated specimens and to test lower respiratory specimens.

Additionally, FDA approved an amendment on July 13, 2020, to add the Promega Maxwell® RSC 48 as an authorized extraction instrument for use with the CDC 2019-nCoV rRT-PCR Diagnostic Panel.

Can we still order CDC's first viral test for SARS-CoV-2, or is the multiplex assay replacing it?

This new test is designed for use at CDC-supported public health laboratories at state and local levels, where it will supplement and streamline surveillance for flu and COVID-19. The use of this specialized test will be focused on public health surveillance efforts and will not replace any COVID-19 tests currently used in commercial laboratories, hospitals, clinics, and other healthcare settings.

CDC's first viral test for SARS-CoV-2 (the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (ER-34)) will still be available for qualified laboratories to order through the International Reagent Resource (IRR) external icon. The new multiplex assay can also be ordered through the IRR. Check the IRR website for details.

For additional questions, please visit: Clinical Questions about COVID-19: Questions and Answers: Testing, Diagnosis, and Notification

Testing Strategies for SARS-CoV-2

What is the difference between diagnostic testing and screening testing for SARS-CoV-2?

Diagnostic testing for SARS-CoV-2 is intended to identify current infection at the individual level and is performed when a person has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2.

Screening testing for SARS-CoV-2 is intended to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2. Screening testing is performed to identify persons who may be contagious so that measures can be taken to prevent further transmission.

Any laboratory or testing site that performs diagnostic or screening testing must have a Clinical Laboratory Improvement Amendments (CLIA) certificate and meet all requirements to perform testing. For more information, see the Centers for Medicare & Medicaid Services (CMS) summary of the CLIA regulations. Assays and test systems used for COVID-19 diagnostic or screening testing must have received an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) or be offered under the policies in FDA's Policy for COVID-19 Tests.

See CDC's Overview of Testing for SARS-CoV-2, and FDA's FAQs on Testing for SARS-CoV-2.

Is there any difference in how results are reported for diagnostic testing versus screening testing?

No. Both diagnostic testing results and screening testing results are reported to the persons whose specimens were tested and/or to their healthcare provider or employer.

In addition, both diagnostic testing results and screening testing results (positive and negative) must be reported to the local, state, tribal, or territory health department in accordance with Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act. On June 4, 2020, the Department of Health and Human Services published guidance on COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 that specifies what additional data laboratories and testing sites should collect and electronically report, in addition to COVID-19 diagnostic or screening test results.

What is the difference between screening testing and surveillance testing?

Screening testing for SARS-CoV-2 is intended to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2. Screening testing is performed to identify persons who may be contagious so that measures can be taken to prevent further transmission.

Public health surveillance is the ongoing, systematic collection, analysis, and interpretation of health-related data essential to planning, implementation, and evaluation of public health practice. See CDC's Introduction to Public Health Surveillance.

Surveillance testing for SARS-CoV-2 is intended to monitor community- or population-level outbreak of disease, or to characterize the incidence and prevalence of disease. Surveillance testing is performed on de-identified specimens, and thus results are not linked to individuals. Surveillance testing cannot be used for individual decision-making.

Any laboratory or testing site that performs **screening testing** must have a Clinical Laboratory Improvement Amendments (CLIA) certificate and meet all requirements to perform testing. For more information, see the Centers for Medicare & Medicaid Services (CMS) summary of the CLIA regulations . Assays and test systems used for COVID-19 screening testing must have received an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) or be offered under the policies in FDA's Policy for COVID-19 Tests .

Laboratories that conduct **surveillance testing** for SARS-CoV-2 are not obligated to comply with the FDA and CLIA requirements for diagnostic and screening testing.

See CDC's Overview of Testing for SARS-CoV-2, and FDA's FAQs on Testing for SARS-CoV-2 .

Is there any difference in how results are reported for screening testing versus surveillance testing?

Yes. Screening results are a specific person's test results, whereas surveillance results are reported in aggregate, or as de-identified individual reports.

Screening testing results are reported to the persons whose specimens were tested or to their healthcare provider or employer. In addition, screening testing results (positive and negative) must be reported to the local, state, tribal, or territory health department.

By contrast, surveillance testing results cannot be reported to the persons whose specimens have been tested, nor to their healthcare provider or employer. Surveillance testing results also should not be officially reported to the local, state, tribal, or territory health department as diagnostic or screening test results. If a local, state, tribal, or territory health department, or another institution, requests access to the results of surveillance testing for SARS-CoV-2, those results may only be reported in aggregate to the requesting institution, and a statement should be included that indicates the data are surveillance testing results that do not represent COVID-19 diagnostic or screening test results.

Can you summarize the difference among these testing strategies?

Summary of Testing Strategies for SARS-CoV-2

	Diagnostic	Screening	Surveillance
Symptomatic or Known or Suspected Exposure	Yes	No	N/A
Asymptomatic without Known or Suspected Exposure	No	Yes	N/A
Characterize Incidence and Prevalence in the Community	N/A	N/A	Yes
Results may be Returned to Individuals	Yes	Yes	No
Results Returned in Aggregate to Requesting Institution	No	No	Yes

Results Reported to State Public Health Department	Yes	Yes	Only if requested; must be in aggregate
Testing can be performed in a CLIA-Certified Laboratory	Yes	Yes	Yes
Testing can be performed in a Non-CLIA-Certified Laboratory	No	No	Yes
Test System Must be FDA Authorized or be Offered under the Policies in FDA's Guidance	Yes	Yes	No

General Guidance and Regulatory Requirements

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 more:

- Important Information on the Use of Serological (Antibody) Tests for COVID-19: FDA Letter to Healthcare Providers
- FDA EUA Authorized Serology Test Performance

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 for COVID-19
- Overview of Testing for SARS-CoV-2 (for healthcare professionals)
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with COVID-19
- CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use
- CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay Instructions for Use

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 .

Can a laboratory without a CLIA certificate conduct surveillance testing? –

Yes. If a laboratory conducts surveillance testing on a specimen without a unique identifier and the results of that testing are not returned to the individual, or to the individual's healthcare provider, employer, etc., that laboratory does not need a CLIA certificate. Surveillance testing results may be returned in aggregate to the institution that requested the study. In such cases, surveillance testing may indicate the need to conduct additional and perhaps more targeted diagnostic testing or screening at the individual level in a CLIA-certified laboratory to improve population or setting-specific health. If at any time a facility conducting surveillance testing intends to report a patient-specific testing result, it must first obtain a CLIA certificate and meet all CLIA requirements to perform that testing.

Test Developers

Can test developers reference the Emergency Use Authorization (EUA) for CDC's diagnostic multiplex assay for flu and SARS-CoV-2 when validating or seeking authorization for a test based on the CDC design? –

Yes. CDC has extended right of reference for manufacturers and clinical laboratories to cite the EUA for CDC's Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay (FDA submission number EUA201781). This means clinical laboratories and commercial manufacturers may avoid repeating studies CDC has already conducted in support of its EUA. CDC has published the primers and probes sequences, so other laboratories and companies may manufacture their own reagents. The sequences are identical to those used for the CDC kit and may be used by commercial manufacturers and clinical laboratories in the design of their own independent assays. These sequences are labeled *research use only* because the primers and probes manufactured from these sequences cannot be used under CDC's EUA. Only primer and probe sets distributed through the International Reagent Resource may be used with the assay under CDC's EUA.

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.

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 antibodies?

Currently, there is no identified performance advantage of assays that test for IgG or IgM antibodies compared to those that test for total immunoglobulin antibodies. Using an assay that tests for IgM antibodies may detect a more recent infection with SARS-CoV-2, but typically both IgM and IgG rise early in SARS-CoV-2 infections. IgM levels do wane earlier than IgG, and thus assays that test IgM alone may not detect prior infection. Scientists from CDC and elsewhere are continuing to investigate SARS-CoV-2 immune responses and immunoglobulin (antibody) persistence over time using either IgG or total antibodies test.

Laboratory Biosafety

How should the laboratory perform a risk assessment to identify and mitigate risks?

All laboratories should perform a site-specific and activity-specific risk assessment to identify and mitigate risks and determine if enhanced biosafety precautions are warranted based on situational needs, such as high testing volumes, and the likelihood to generate infectious droplets and aerosols. Risk assessments and mitigation measures are dependent on the procedures performed, identification of the hazards involved in the process and/or procedures, the competency level of the personnel who perform the procedures, the laboratory equipment and facility, and the resources available.

The risk assessment should identify all potential scenarios of a particular activity that could produce a negative outcome. The risk assessment should prioritize those potential negative outcomes, or risks, based on an evaluation of the likelihood and consequences of each of those identified risks. The risk assessment should determine the most appropriate control measures, and how the system will measure the effectiveness of those control measures.

For additional information, refer to the following:

- Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV)
- Risk Assessment Best Practices
- World Health Organization Laboratory Biosafety Manual, 3rd

Are certified Class II biological safety cabinets (BSCs) required to process suspected or confirmed SARS-CoV-2 specimens? Should laboratory staff put procedures in place to minimize personnel exposure if there is no certified Class II BSC?

For procedures with a high likelihood to generate aerosols or droplets, use either a certified Class II Type A1 or A2 BSC or additional precautions to provide a barrier between the specimen and personnel. Examples of these additional precautions include personal protective equipment (PPE), such as a surgical mask or face shield, or other physical barriers, like a splash shield; centrifuge safety cups; and sealed centrifuge rotors to reduce the risk of exposure to laboratory personnel.

For additional information, refer to the following:

- CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
- Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV)

How should point-of-care testing (POCT) be conducted outside a traditional laboratory?

For viral testing of specimens conducted outside of a traditional clinical laboratory, such as rapid respiratory testing, use Standard Precautions to provide a barrier between the specimen and personnel during specimen manipulation.

For additional information, refer to:

- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)

If laboratory personnel collect blood or respiratory specimens directly from suspected or confirmed COVID-19 patients, what PPE should they wear?

If laboratory personnel have direct contact with suspected or confirmed COVID-19 patients, they should follow recommended PPE for health care providers while in the presence of these patients.

For additional information, refer to:

- Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings
- OSHA 29 CFR 1910.1030 Bloodborne Pathogens Standard

What is the recommended biosafety level for handling suspected or confirmed SARS-CoV-2 patient specimens?

Routine viral testing of patient specimens, such as the following activities, can be handled in a BSL-2 laboratory using Standard Precautions:

- Using automated instruments and analyzers
- Staining and microscopic analysis of fixed smears
- Examination of bacterial cultures
- Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
- Molecular analysis of extracted nucleic acid preparations
- Final packaging of specimens for transport to diagnostic laboratories for additional testing. Specimens should already be in a sealed, decontaminated primary container
- Using inactivated specimens, such as specimens in nucleic acid extraction buffer
- Electron microscopic studies with glutaraldehyde-fixed grids

For additional information, refer to the following:

- CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
- OSHA 29 CFR 1910.1030 Bloodborne Pathogens Standard

What disinfectant should personnel use to decontaminate work surfaces?

Decontaminate work surfaces and equipment with appropriate disinfectants. Use EPA-registered hospital disinfectants with label claims to be effective against SARS-CoV-2 . Follow manufacturer's recommendations for use, such as dilution, contact time, and safe handling.

How should specimens be stored?

Store specimens at 2-8°C for up to 72 hours after collection. If a delay occurs in extraction, store specimens at -70°C or lower. Store extracted nucleic acid samples at -70°C or lower.

For additional information, refer to the following:

- Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings
- CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel

How should laboratory personnel remove biohazardous waste from the laboratory or testing area for decontamination and disposal?

Handle laboratory waste from testing suspected or confirmed COVID-19 patient specimens as all other biohazardous waste in the laboratory. Currently, there is no evidence to suggest that this laboratory waste needs additional packaging or disinfection procedures.

For additional information, refer to the following:

- Biosafety in Microbiological and Biomedical Laboratories (BMBL) (5th edition)

What are Standard Precautions?

Standard Precautions are the minimum infection prevention practices that apply to patient care, regardless of suspected or confirmed infection status of the patient, in any setting where health care is practiced. They are based on the principle that there is a possible risk of disease transmission from any patient, patient sample, or interaction with infectious material. Standard Precautions include hand hygiene and use of personal protective equipment (PPE) when indicated, in addition to practices to ensure respiratory hygiene, sharps safety, safe injection practices, and effective management of sterilization and disinfection for equipment and environmental surfaces. The exact implementation of Standard Precautions should be determined by an activity-specific risk assessment.

For additional information, refer to the following:

- 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
- CDC Isolation Precautions

What are infectious aerosols and droplets?

Aerosols and droplets containing particles that are <100 µm in diameter are not visible to the naked eye. Laboratory workers may not be aware that such particles can be generated during many laboratory procedures and that these particles could be inhaled or could cross-contaminate work surfaces, materials, and equipment.

Infectious aerosols are small liquid or solid particles suspended in the air that contain infectious agents. They can disperse throughout the laboratory and remain infective over time and distance. These particles are of a size that may be inhaled into the lower respiratory tract (<5 µm in diameter). Examples of organisms transmitted by aerosols include spores of Aspergillus spp., Mycobacterium tuberculosis, rubeola virus (measles), and varicella-zoster virus (chickenpox).

Droplets traditionally are defined as larger infectious particles (>5 µm in diameter) that rapidly fall out of the air, contaminating gloves, the immediate work area, and the mucous membranes of the persons performing the procedure.

Examples of infectious agents that are transmitted via the droplet route include Bordetella pertussis, influenza viruses, adenovirus, Mycoplasma pneumoniae, SARS-associated coronavirus (SARS-CoV), group A streptococcus, and Neisseria meningitidis.

For additional information, refer to the following:

- WHO Laboratory Biosafety Manual, 3rd
- 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
- CDC Isolation Precautions

What procedures can generate aerosols and droplets?

Many routine laboratory procedures can potentially generate aerosols and droplets that are often undetectable. The following laboratory procedures have been associated with the generation of infectious aerosols and droplets: centrifugation, pipetting, vortexing, mixing, shaking, sonicating, removing caps, decanting liquids, preparing smears, flaming slides, aliquoting and loading specimens, loading syringes, manipulating needles, syringes or sharps, aspirating and transferring blood and body fluids, subculturing blood culture bottles, spilling specimens, and cleaning up spills.

For additional information, refer to the following:

- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories
- Biosafety in Microbiological and Biomedical Laboratories, 5th Ed.
- Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV)

When is it appropriate to transport suspected or confirmed SARS CoV-2 specimens by pneumatic tube?

It depends on the type of specimen being transported:

- CDC recommends that respiratory specimens from patients with suspected or confirmed COVID-19 should not be transported through pneumatic tubes. At this time, this recommendation only applies to suspected or confirmed COVID-19 respiratory specimens. Examples of respiratory specimens include nasopharyngeal (NP) and oropharyngeal (OP) swabs, nasal mid-turbinate (NMT) swabs, tracheal and lower respiratory tract aspirates, bronchoalveolar lavage (BAL) specimens, and sputum.
- Based on currently available data, other types of specimens from patients with suspected or confirmed COVID-19, such as blood, urine, and feces specimens, are still acceptable to transport through pneumatic tubes.

Facilities should ensure that all personnel who transport specimens via pneumatic tubes are trained in safe handling practices, specimen management, and spill decontamination procedures.

Each facility should also evaluate its risks and determine the most appropriate biosafety measures and practices to implement.

For additional information, refer to the following:

- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories MMWR, Supplement / Vol. 61 January 6, 2012

How should decentralized and point-of-care (POC) testing for COVID-19 diagnostic purposes be conducted outside of a traditional laboratory?

Testing sites that operate a POC diagnostic instrument must have a current Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate. During the COVID-19 public health emergency, the Centers for Medicare & Medicaid Services (CMS) will permit a laboratory to extend its existing Certificate of Waiver to operate a temporary COVID-19 testing site in an off-site location (e.g., long-term care or correctional facilities). The temporary COVID-19 testing site is only permitted to perform waived tests, consistent with the laboratory's existing CLIA certificate, and must be under the direction of the existing laboratory director.

Laboratories should consider the following when using POC instruments for COVID-19 diagnostic purposes:

- Use the instrument in a location that has a current CLIA certificate.
- Perform a site-specific and activity-specific risk assessment to identify and mitigate safety risks.
- Train staff on the proper use of the instrument and ways to minimize their risk of exposure.
- Follow Standard Precautions when handling clinical specimens, including hand hygiene and the use of PPE, such as laboratory coats or gowns, gloves, and eye protection. If needed, additional precautions can be used, such as a surgical mask or face shield, or other physical barriers, such as a splash shield to work behind.
- When using patient swabs, minimize contamination of the swab stick and wrapper by widely opening the wrapper before placing the swab back into the wrapper.
- Change gloves after adding patient specimens to the instrument.
- Decontaminate the instrument after each run by using an EPA-approved disinfectant for SARS-CoV-2 and following the manufacturer's recommendations for use, including dilution, contact time, and safe handling.

For additional information, refer to:

- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
- Fact Sheet: Guidance – Proposed Use of Point-of-Care (POC) Testing Platforms for SARS-CoV-2 (COVID-19)

What safety issues are there with PrimeStore® Molecular Transport Medium (MTM) when used with SARS-CoV-2 testing platforms?

PrimeStore® MTM transport media contains guanidine thiocyanate, which produces a dangerous chemical reaction that releases cyanide gas when exposed to bleach (sodium hypochlorite). The PrimeStore® MTM transport media being provided by state health departments is currently labeled at the bulk box level, but individual vials lack labels to warn users of the reactive ingredient.

Do NOT use PrimeStore® MTM with any Real-Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) platforms that include a disinfecting step that uses bleach (e.g., Panther® Hologic, Panther Fusion® Systems).

In addition to its reactivity, PrimeStore® MTM may be harmful by inhalation, in contact with skin, and if swallowed. Wear appropriate personal protective equipment (PPE) as required by your laboratory protocols, including laboratory coat, safety glasses, and gloves. Dispose of product content and container in accordance with all local, regional, national, and international regulations. Untreated waste should not be disposed into the sewer unless fully compliant with all applicable requirements. See the Material Safety Data Sheet for disposal information.

For more information, see the Longhorn PrimeStore® Molecular Transport Medium Fact Sheet .

What safety issues can occur when using a mixture of A549 and Mv 1 Lu cell lines (also referred to as A549/Mv 1 Lu mix or R-Mix™) for culturing respiratory viruses?

It has been shown that Mv 1 Lu cells can support low level replication of SARS-CoV, which could result in the inadvertent growth of SARS-CoV-2. Therefore, CDC recommends that laboratories **discontinue the use** of the A549/Mv 1 Lu mix (R-Mix™) or any other mixture containing Mv 1 Lu cell lines.

Based on recent publications, (Severe Acute Respiratory Syndrome Coronavirus 2 from Patient with Coronavirus Disease, United States), A549 and MDCK cells lines (which make up R-Mix Too™) do not support SARS-CoV-2 replication. As a result, R-Mix Too™ may be considered for use as an alternative for R-Mix™.

For additional information, see

SARS-associated Coronavirus Replication in Cell Lines

Severe Acute Respiratory Syndrome Coronavirus 2 from Patient with Coronavirus Disease, United States

Specimen Packing and Shipping

Do people packing patient specimens, isolates or cultures for transport need to be trained and competent?

For transporting patient specimens, cultures or isolates, personnel must be trained in the proper safety, packing, and shipping regulations for Division 6.2, UN 3373 Biological Substance, Category B in accordance with the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations (DGR). Personnel should be trained in a manner that corresponds to their function-specific responsibilities.

For additional information, refer to the following:

- Guidance on regulations for the transport of infectious substances 2019 – 2020

What specific packaging should personnel use when shipping suspected or confirmed SARS-CoV-2 patient specimens, isolates or cultures?

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 Dangerous Goods Regulations Packaging Instruction 650
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
- Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV)

At what temperature should specimens be shipped?

Specimens should be shipped at 2-8°C with ice packs. If the specimen is frozen, ship overnight on dry ice. The primary receptacle and the secondary packaging should maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures which could result if refrigeration were lost. Packages containing dry ice should be designed and constructed so as to prevent the buildup of pressure and to allow the release of gas that could rupture the packaging.

For additional information, refer to the following:

- CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)

What information is required on the outer package for shipment of specimens with ice packs?

A: Ensure the outer package has been properly marked and labeled with the following:

1. Hazard labeled with UN Identification Number already on label – UN 3373
2. Biological Substance, Category B
3. Shipper's name, address, and phone number
4. Receiver's name, address, and phone number
5. Name and phone number of a responsible person is optional if it is on the airway bill

For additional information, refer to the following:

- Guidance on regulations for the transport of infectious substances 2019 – 2020
    - Dangerous Goods Documentation
    - Click on "Infectious substances" and there is an option to download the packing instructions.
- Labels for UN 3373
    - When using cold pack – Include the name and telephone number of the person who will be available during normal business hours who knows the content of the shipment (can be someone at CDC). Place the label on one side of the box and cover the label completely with clear tape (do not tape just the edges of the label).
- Schematic for packaging, UN 3373 Category B

What information is required on the outer packages for shipment of specimens with dry ice?

Ensure the outer package has been properly marked and labeled with the following:

1. Hazard labeled with UN Identification Number already on label – UN 3373
2. Biological Substance, Category B
3. Hazard Labeled with UN Identification Number- UN 1845
4. Dry Ice along with the net weight (kg) of the dry ice
5. Shipper's name and address
6. Receiver's name and address
7. Name and phone number of a responsible person.

For additional information, refer to the following:

- Guidance on regulations for the transport of infectious substances 2019 – 2020
- IATA Dangerous Goods Regulations Packaging Instruction 650
    - Packing Instructions 650 for UN 3373
  - Click on "Infectious substances" and there is an option to download the packing instructions.
- Labels for UN 3373
  - When using dry ice – Include the name and telephone number of the person who will be available during normal business hours who knows the content of the shipment (can be someone at CDC). Place the label on one side of the box and cover the label completely with clear tape (do not tape just the edges of the label).
- Schematic for packaging, UN 3373 Category B

What information is required on an overpack if used for specimen shipment?

The overpack should be marked in accordance with the packing instructions required for the outer package:

1. Hazard labeled with UN Identification Number already on the label – UN 3373
2. Biological Substance, Category B
3. Shipper's name, address, and phone number
4. Receiver's name, address, and phone number
5. Package Orientation Label
6. Marked with the word "Overpack"
7. Name and phone number of a responsible person is optional if it is on the airway bill

For additional information, refer to the following:
• IATA Dangerous Goods Regulations Packaging Instruction 650
• Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)

Is a shipper's declaration required? What documentation is required for shipment? What if specimens are shipped on dry ice?

A shipper's declaration is not required for UN 3373 Biological Substances, Category B shipped samples. If an Air Waybill is used, the "Nature and Quantity of Goods" box should show "UN 3373 Biological Substance, Category B" along with the number of packages. If specimens are shipped on dry ice, include UN 1845, Dry Ice, 9, along with the net weight of the dry ice. See IATA PI 650 for additional information.

For additional information, refer to the following:

- Guidance on regulations for the transport of infectious substances 2019 – 2020
- IATA Dangerous Goods Regulations Packaging Instruction 650

Is a Responsible Person required on the shipping paperwork?

Yes, a Responsible Person should be listed on the air waybill or Shipper's Declaration (if applicable).

For additional information, refer to the following:

- Guidance on regulations for the transport of infectious substances 2019 – 2020
- IATA Dangerous Goods Regulations Packaging Instruction 650

Once packaging of the samples is complete should staff members decontaminate the work area?

Decontaminate work surfaces and equipment with appropriate disinfectants. Use EPA-registered hospital disinfectants with label claims to be effective against SARS-CoV-2. Follow manufacturer's recommendations for use, such as dilution, contact time, and safe handling.

For additional information, refer to the following:

- Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus 2019 (COVID-19) in Healthcare Settings
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)

Specimen Types

Are stool specimens appropriate for SARS-CoV-2 viral testing?

Stool specimens do not have Emergency Use Authorization (EUA) approval and thus are not acceptable for SARS-CoV-2 viral testing. Although data are limited, they indicate that stool might not be an appropriate specimen. Stool specimens are less sensitive than respiratory specimens, and SARS-CoV-2 RNA is often detected later during COVID-19 illness. Therefore, testing stool early in illness could potentially lead to false negative SARS-CoV-2 viral test results. Also, even though viral tests have detected SARS-CoV-2 RNA in stool (i.e., a positive test), infectious virus has only been confirmed very rarely, if at all in samples. In other words, a positive SARS-CoV-2 test does not necessarily mean a patient is currently infected and can infect others.

Interpreting Results of Diagnostic Tests

What influences the likelihood of false-positive or false-negative diagnostic test results?

The likelihood of obtaining a false-positive or false-negative diagnostic test result is influenced by factors related to the testing scenario and the test being used (e.g., sensitivity and specificity of the diagnostic test). Diagnostic tests perform optimally for detecting an infection when the **pretest probability** is high. Pretest probability is the likelihood that the person being tested actually has the infection. This likelihood is based on both the proportion of people in the test population or group who have the infection at a given time (prevalence) and the clinical presentation (including symptoms and known exposure) of the person being tested. In other words, the pretest probability increases with increasing prevalence in the population and clinical indications of illness in the person being tested. In contrast, tests typically perform best for excluding an infection when the pretest probability is low**. Test sensitivity** is the ability of a test to correctly identify persons with infection, whereas **test specificity** is the ability to correctly rule-out infection.

What factors have the greatest impact on false-positive rates?

Positive predictive value is the probability that a person who has a positive test result most likely has the infection. Pretest probability and test specificity have the greatest impact on false-positive rates. As the pretest probability and the specificity of the test increases, the false-positive rate decreases and the positive predictive value increases.

What factors have the greatest impact on false-negative rates?

Negative predictive value is the probability that a person who has a negative test result most likely does not have the infection. Pretest probability and test sensitivity have the greatest impact on false-negative rates. As the pretest probability decreases, the false-negative rate decreases and the negative predictive value increases. As the sensitivity of the test increases, the false-negative rate decreases and the negative predictive value increases.

What is the relationship between pretest probability and positive and negative predictive values?

Relationship between pretest probability and positive and negative predictive values			
Pretest Probability*	**Negative Predictive Value****	**Positive Predictive Value****	**Impact on Test Results**
Low	High	Low	Increased likelihood of False Positives Increased likelihood of True Negatives
High	Low	High	Increased likelihood of True Positives Increased likelihood of False Negatives

*Sensitivity and specificity of tests are not affected by the pretest probability

**Predictive values are affected by the pretest probability

Do all reverse transcriptase-polymerase chain reaction (RT-PCR) diagnostic tests for SARS-CoV-2, the virus that causes COVID-19, detect the same thing?

All RT-PCR tests for SARS-CoV-2 detect genetic material from the virus. However, among the available diagnostic RT-PCR tests, the nucleic acid target within the SARS-CoV-2 genome varies.

Can a diagnostic RT-PCR test show how infectious someone is?

No. RT-PCR tests are used to identify and diagnose an active infection but cannot be used to show how infectious someone is. Get more information about when you can be around others if you had COVID-19.

What is a cycle threshold (Ct) value from a RT-PCR test?

To improve the test's ability to detect virus, an RT-PCR test creates many copies of the same genetic material from the virus in a process called amplification. The cycle threshold (Ct value) is the point at which a reaction reaches a fluorescent intensity above background levels. The Ct value indicates when the nucleic acid target is detectable in the amplification process. There is a correlation between the Ct value and the amount of viral genetic material that was present in the specimen.

Can a Ct value determine how much viral genetic material is present in an individual patient specimen?

A Ct value does not indicate how much virus is present, but only whether or not viral genetic material was detected at a defined threshold. RT-PCR tests can be either ***qualitative*** or ***quantitative***, and this affects how a Ct value is interpreted. As of October 23, 2020, all diagnostic RT-PCR tests that had received a U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for SARS-CoV-2 testing were ***qualitative*** tests.

1. In a ***qualitative*** RT-PCR test, known amounts of virus are used during the development of the test to determine what Ct values are associated with positive and negative specimens. A Ct value is generated when testing a patient specimen. The Ct value is interpreted as positive or negative but cannot be used to determine how much virus is present in an individual patient specimen.
2. In a ***quantitative*** RT-PCR test, a range of known numbers of genome copies, called reference samples, are tested alongside each RT-PCR reaction. By comparing the Ct value of a patient specimen to the Ct values from the reference samples, the test can calculate the copy number of target nucleic acid. The correlation between Ct value and viral load can be used in evaluating data from groups of people in categories such as symptomatic or asymptomatic and can be applied to infer the difference in the relative amount of viral load between the two. Although a quantitative RT-PCR test can estimate the level of viral load in a population, a quantitative RT-PCR test cannot determine how much virus is present in an individual patient specimen.

Can a Ct value predict how infectious an individual with COVID-19 is?

No. Ct values should not be used to determine a patient's viral load, how infectious a person may be, or when a person can be released from isolation or quarantine.

An RT-PCR test uses multiple repeating amplification cycles to create more and more copies of the virus' genetic material. Specimens with lower amounts of virus will require more cycles to amplify that genetic material to reach an amount that can be detected, resulting in a higher Ct value. Thus, there is a correlation between the Ct value and the amount of starting viral genetic material that was present in the specimen.

For both qualitative and quantitative RT-PCR assays, the correlation between Ct values and the amount of virus in the original specimen is imperfect. It is therefore problematic to infer any relationship between an individual patient's Ct value and their viral load. Ct values can also be affected by factors other than viral load. For example, if the specimen is not collected or stored properly or the specimen is collected early during the infection, the Ct value may be higher than it would be under ideal conditions. Thus, a high Ct value could also result from factors **not** related to the amount of virus in the specimen. The correlation between Ct and viral load can be used to evaluate data from groups of people and infer the difference in the relative amount of viral load between the two groups (e.g., between symptomatic and asymptomatic individuals).

If a Ct value can be affected by factors like specimen collection, how do I know if my RT-PCR test result is accurate?

In addition to detecting SARS-CoV-2 genetic material, each RT-PCR diagnostic test also detects a small portion of a patient's genome. Detecting the patient's genetic material in the specimen confirms the quality of the specimen and the processing steps of the test. If the patient's genetic material is detected, then we can be reasonably sure that the viral genetic material was not degraded, and the test result is accurate.

Can Ct values from different RT-PCR tests be compared?

No. For a given RT-PCR diagnostic test, the genetic material from a patient sample must be processed using a specific series of steps to produce a valid test result. However, the steps used to process the genetic material, the specific genetic target being measured, and the amount of the patient sample used varies among RT-PCR tests. Because the nucleic acid target (the pathogen of interest), platform and format differ, Ct values from different RT-PCR tests cannot be compared.

Anatomic Pathology

What are the anatomic pathology best practices to prevent COVID-19 exposure while performing procedures and processing specimens?

Manual processing of fresh unfixed specimens, including frozen sections, should be conducted in a manner that provides a barrier between the specimen and personnel during specimen manipulation. In addition, protect the mucous membranes of the eyes, nose, and mouth during procedures that are likely to generate **splashes, sprays, droplets, and aerosols.** Examples of these barriers include:

- Performing tissue dissection in a certified Class II A1 or A2 biological safety cabinet (BSC) if available
- Working behind a splash shield
- Using combinations of PPE, such as:
  - surgical mask with attached eye shield
  - surgical mask and goggles
  - mask and a face shield that fully cover the front and sides of the face
  - double gloves or mesh cut-resistant gloves
  - surgical scrubs, shoe covers, full gown, plastic apron, and hair covering
  - N95 respirators or powered air-purifying respirators (PAPRs) (the use of respiratory protection requires fit testing and appropriate training)

What precautions should clinical and non-clinical support staff take when handling specimen containers that may be contaminated with blood and body fluids?

All laboratories should perform a site- and activity-specific risk assessment and follow Standard Precautions when handling specimen containers and paper requisitions that could have been contaminated by tissue and fluid specimens. This risk assessment may suggest use of some of these mitigation strategies:

- Use face shields and/or work behind a splash guard whenever possible.
- Store human specimens in closed containers that can be decontaminated before moving them to a secure area.

Place specimen containers in closed and clearly labeled plastic bins until pick-up and disposal according to your institutional waste management policies.

What are the biosafety recommendations for performing frozen sectioning on confirmed and suspected COVID-19 patient specimens?

Avoid frozen sectioning from confirmed COVID-19 patients whenever possible. Talk with the relevant clinical and surgical teams about the clinical necessity and benefit of frozen sectioning and consider appropriate alternatives for suspected and confirmed COVID-19 cases. When frozen sectioning is unavoidable, the following are recommended, if possible:

- Receive specimens in an area apart from administrative staff
- Consider using a cryostat that has a downdraft and other safety features.
- Use cryostats in a closed room that has inward directional (negative) airflow vented directly to the outside or recirculated through a HEPA filter to avoid contaminating the rest of the surgical pathology suite.
- Provide grossing rooms with inward directional air flow.
- Reduce the number of operators to a minimum.
- Wear appropriate PPE, including but not limited to:
  - Fluid-resistant disposable double gloves and gown,
  - Fluid-resistant disposable apron,
  - Eye protection (face shield or goggles), and
  - N95 respirator or fluid-resistant surgical mask.
- Do not use freezing sprays; they are not recommended by the manufacturers of cryostat instrumentation.
- Wear cut-resistant, stainless steel mesh gloves during disassembly, cleaning, and disinfection of microtome knives.
- Collect accumulated instrument shavings and discard them as biohazardous waste.
- Follow local standard decontamination procedures of the cryostat and other surfaces. Ultraviolet lights are not a substitute for terminal cleaning of the instrument.

For additional information, refer to the following:

- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories

What chemical treatments inactivate SARS-CoV-2 in tissues during histopathology processing?

Human tissues submitted for permanent pathologic examination typically undergo several processing steps with chemicals that have been shown to inactivate coronaviruses:

- Studies with SARS-CoV-1 and MERS-CoV have shown that virus inactivation for these coronaviruses occurs in a time-dependent fashion with both formalin fixation and temperatures of 56°C or above.
- Alcohol at 70% concentration or higher has been shown to inactivate the virus and tissue processing typically includes a series of alcohol dehydration steps that use 70% to 100% alcohol prior to paraffin embedding.
- In addition, the final step of applying a glass or plastic coverslip to the slide provides an additional barrier between the personnel and the tissue.

For additional information, refer to the following:

Inactivation of the coronavirus that induces severe acute respiratory syndrome, SARS-CoV

Inactivation and safety testing of Middle East Respiratory Syndrome Coronavirus

Practical Guide to Specimen Handling in Surgical Pathology

Coronavirus disinfection in histopathology

NSH-COVID-19: Novel Coronavirus Resources

Does a grossing station that draws air and fumes toward the rear of the unit offer the same protection as a biosafety cabinet?

No. Grossing stations pull formalin fumes away from the person who is doing the dissecting. In general, grossing stations are not as effective as biosafety cabinets at protecting the user from exposure to biological agents.

For additional resources related to biological safety cabinets, refer to:

- Fundamentals of Working Safely in a Biological Safety Cabinet provides free training CEU
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition Section III_ Biological Safety Cabinets (page 292).

Ordering Supplies (For Public Health Laboratories)

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 testing for SARS-CoV-2?

The catalog of SARS-CoV-2 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, 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?

All CDC test kits associated with current EUAs will be available to order through IRR for the duration of the emergency response. Commercial reagents may be added or removed from the IRR catalog as needed to ensure equitable nationwide testing.

What is the new process for swab ordering?

The US Department of Health and Human Services (HHS) is directly managing allocation of swabs and media, including viral transport medium (VTM), based on state and territory testing plans that were submitted in response to the Coronavirus Aid, Relief, and Economic Security (CARES) Act requirements. Allocations were predetermined to maximize state and territory testing using a data-driven algorithm based on population, high incidence areas, and COVID-19 Task Force's directives. Currently, HHS is distributing the following swabs: nasopharyngeal (NP), nasal, foam, and poly swabs. HHS is distributing the following media: saline, phosphate buffered saline solution (PBS), and VTM. For specific swab or medium requests, delivery site changes, or other related requests contact COVID19TestSupplies@hhs.gov.

Ordering Supplies (For Clinical Laboratories)

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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