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

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What are you looking for?

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General Guidance and Regulatory Requirements

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 or other facility that performs testing 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 Emergency Use Authorization (EUA)?

Tests for SARS-CoV-2 that are offered prior to or without an EUA have not been reviewed by the Food and Drug Administration (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.”

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.

How does my laboratory assess the validity of a specimen that has been obtained through self-collection?

Self-collection of specimens, both unsupervised and supervised by a medical professional, is currently available for specific tests authorized by the FDA. Additional authorized diagnostic tests for the detection of SARS-CoV-2 will likely have this capability as well.

There have been reports of fraudulent specimens being submitted to laboratories for testing, often as a result of unsupervised collection and travel- or work-related requirements. Laboratories should make every effort to confirm the specimen has been obtained correctly and from the individual that is being tested. Generally, CLIA requires laboratories to ensure positive specimen identification and optimum integrity of a patient's specimen using at least two separate (distinct) or unique identifiers, such as patient's name or another unique identifier. Other information that must be provided to the laboratory when requesting a test includes the sex and age or date of birth of the patient; the test(s) to be performed; the specimen source; the date and, if appropriate, the time of specimen collection.

Test Developers

Can test developers reference the 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 test 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. 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 the National Institutes of Health's (NIH) 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.

Laboratory Biosafety

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) (6th 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 specimen, 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
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) (6th edition)
- Standard Precautions for All Patient Care

What are infectious aerosols and droplets?

What are infectious aerosols and droplets?

Aerosols and droplets containing particles <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. 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).

Infectious droplets are traditionally defined as larger 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 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, 4th Edition
- 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. For example, 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 (BMBL) (6th edition)
- 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?

CDC recommends that each laboratory perform a risk assessment before using the pneumatic tube system to transport suspected or confirmed COVID-19 specimens. Each facility should conduct a site- and activity-specific risk assessment of the procedures performed, identifying the hazards involved in the process, the competency level of the personnel performing the methods, and the laboratory facility. Your institution's biosafety professional, laboratory management, scientific/clinical, and safety staff should be involved in conducting the risk assessment process to determine the appropriate specimen transport practices to implement at your facility.

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

For additional information about performing a risk assessment, refer to the Biological Risk Assessment: General Considerations for Laboratories and the Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition , Section II – Biological Risk Assessment, pages 9-20.

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

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® MTM 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

Should individuals packing 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:

- WHO Guidance on regulations for the transport of infectious substances 2019 – 2020
- APHL Packaging and Shipping Evaluation Tool
- APHL Packing and Shipping Infectious Substances Training Requirements Job Aid
- APHL Packing and Shipping Guidance for Biological Substances, Category B Specimens

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 Packing Instruction 650
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
- WHO Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV)
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) (6th edition)
- SARS-CoV-2 Specimens: Packing and Shipping

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?

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:

- WHO Guidance on regulations for the transport of infectious substances 2019 – 2020
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  - Dangerous Goods Documentation
  - Click on "Infectious substances" and there is an option to download the packing instructions.
- Labels for UN 3373
  - When using cold packs – 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/Consignee name and address
7. Name and phone number of a responsible person.

For additional information, refer to the following:

- WHO Guidance on regulations for the transport of infectious substances 2019 – 2020
- IATA Dangerous Goods Regulations Packing 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/Consignee 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 Packing 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 specimens. 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:

- WHO Guidance on regulations for the transport of infectious substances 2019 – 2020
- IATA Dangerous Goods Regulations Packing 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:

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

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

Decontaminate work surfaces and equipment with appropriate disinfectants. Use EPA-registered disinfectants with label claims that they are 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:

- EPA Resource Conservation and Recovery Act (RCRA) Regulations
- 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)

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

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

No. RT-PCR tests are used to identify and diagnose an active infection and cannot be used to show how infectious an individual person 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, a 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 August 5, 2021, all diagnostic RT-PCR tests that had received a US Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for SARS-CoV-2 testing were ***qualitative*** tests. 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.

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 may 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.

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

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

Although there is an association between Ct value and amount of genetic material, 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 the Ct value and viral load for a person's specimen, and whether the virus is infectious or non-infectious. Ct values can also be affected by many 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 may 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, or between vaccinated and unvaccinated 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 person's genome. Detecting the genetic material in the specimen confirms the quality of the specimen and the processing steps of the test. If the genetic material is detected, then we can be reasonably sure the specimen was not compromised, and the test result is accurate.

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

For a given RT-PCR diagnostic test, the genetic material from a patient specimen 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 specimen 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.

Can Ct values be used at a population level for public health surveillance purposes?

Yes. Although specific Ct values should not be included in a person's health record or used to influence a person's individual care, median Ct values from a population or group may be valuable for public health to evaluate viral load and transmissibility for a particular SARS-CoV-2 variant, or to compare the viral load between two groups (e.g., between vaccinated and unvaccinated individuals).

Anatomic Pathology

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.

What practices should be followed to prevent SARS-CoV-2 exposure when processing specimens and performing test procedures in anatomic pathology?

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 appropriate training and evaluation)

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 dispose 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 of specimens from persons with confirmed COVID-19 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 airflow.
- 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)
  - 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
- CAP Practical Guide to Specimen Handling in Surgical Pathology
- Coronavirus disinfection in histopathology
- NSH-COVID-19: Novel Coronavirus Resources for Histology Labs

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) (6th edition) Appendix A, Section III_Biological Safety Cabinets (page 370).

Ordering Supplies (For Clinical and Public Health Laboratories)

What is the new process for swab ordering?

The US Department of Health and Human Services (HHS) is directly managing allocation of some swabs and media, including viral transport media (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. A monthly web-based survey goes out to each state and territory where they can request the amount

of swabs and media required. As of August 2021, HHS is distributing the following swabs: nasopharyngeal (NP), nasal

I can't find 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 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 Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay. Check the Instructions for Use to see which transport medium is acceptable.

Ordering Supplies (For Public Health Laboratories)

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

The International Reagent Resource (IRR) 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 to public health laboratories for use in 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 supported and quality control of the reagents is assured.

IRR has supported the COVID-19 emergency response since February 2020, with a catalog expansion from April to December 2020, to provide more products needed for viral testing, including numerous commercially produced 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?

IRR provides CDC-manufactured kits and controls associated with its EUA applications to registered public health laboratories that perform SARS-CoV-2 testing.

Commercial reagents may be added or removed from the IRR catalog as needed to ensure equitable nationwide testing. For a complete list of IRR's currently available items, visit IRR's FAQ page.

Can I register my lab or hospital with IRR?

CDC limits IRR registration and SARS-CoV-2 diagnostic reagent distribution to US 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. Qualified laboratories must have the appropriate certifications (CLIA) to serve as a diagnostic laboratory as well as appropriate equipment, training, and demonstration of testing proficiency under their state laboratory's stewardship.

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