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**Topic:** Navigating SARS-CoV-2 Test Implementation Webinar  
**Date:** June 11, 2020  
**Subject:** Questions and Answers

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### **Biosafety Issues**

**1. Does CAP require a biosafety risk assessment prior to performing SARS-CoV-2 testing?**

No, the laboratory is not required to perform a biosafety risk assessment prior to performing SARS-CoV-2 testing; however, it is a very effective tool to determine if appropriate safety measures are in place and to identify needed risk mitigation strategies.

**2. If we decide to use a BSC, what's the recommended minimum safety level class of biological safety cabinet?**

The CAP requirements do not specify the type of biologic safety cabinet for use or mandate that one must be used. For procedures with a high likelihood of generating droplets or aerosols, the CDC recommends using either a certified Class II biological safety cabinet or additional precautions (e.g., PPE, such as surgical mask, face shield, splash shield) to provide a barrier between the specimen and personnel.

You may wish to review the CAP's Best Practices for Using Biological Safety Cabinets While Testing for COVID-19 ([https://documents.cap.org/documents/28683\\_Best-PracticeBiologic-Cabinet-FINAL.pdf](https://documents.cap.org/documents/28683_Best-PracticeBiologic-Cabinet-FINAL.pdf)) for additional information on use of BSC.

**3. Do you have to use eye protection if doing test in the BSC?**

The laboratory must follow their established policies/procedures for the use of PPEs. It would be up to the laboratory director to determine if the use of eye protection is necessary when working under the BSC that has a working and functioning sash that can be lowered to ensure splashing or aerosolization cannot occur.

**4. What are the safety considerations if my laboratory ships specimens to another laboratory 400 miles away?**

Proper training of personnel on packing of specimens is essential. 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)<sup>external icon</sup>:

A leakproof primary container. A leakproof, watertight secondary packaging with absorbent material. A rigid outer packaging to protect the specimens during shipment. The laboratory will also want to ensure that the sample integrity is maintained during shipping.



For couriers transporting specimens (GEN.40515) these requirements for packaging and shipping of infectious substances do not apply. The couriers need to be trained on handling specimens for the specimen type and distance transported, but they may not actually be doing packaging.

**5. Are there any special requirements for COVID 19 samples discarded after using?**

Laboratories should review national, federal, state (or provincial), and local guidelines for the handling of samples from patients suspected to have high risk pathogens such as avian influenza, MERS coronavirus, SARS coronavirus, or COVID-19 coronavirus. (GEN.74050) All infectious wastes (e.g., glassware, blood collection tubes, microbiologic and tissue specimens) and other solid or liquid waste or refuse are discarded into "biohazard"- labeled containers that do not leak and have solid, tight-fitting covers that are applied before transport from the laboratory work area for storage and disposal. (GEN.77900)

**Personnel**

**1. Is competency required to be done for the staff before the staff starts to perform the EUA test?**

Personnel must satisfactorily complete training prior to performing patient testing as required in GEN.55450. Competency assessment is not required prior to performing patient testing; however, it must be evaluated at the frequency required in the checklists depending on the complexity of testing and whether the testing is performed by new testing personnel or existing testing personnel. Please refer to GEN.55500 for nonwaived testing and GEN.55499 for waived testing for more information.

**2. There are numerous labs using lab personal not qualified to perform the test in hospital setting. I was told they can perform the test under supervision of qualified pathologist.**

The laboratory must follow the FDA classification of testing. If the FDA has deemed a test as high-complexity testing, the testing personnel must qualify as high-complexity testing personnel. Testing personnel qualifications for nonwaived testing can be found under GEN.54750.

**Quality Monitoring**

**1. What is the recommended timeframe to perform PT once your lab has started testing patient samples?**

There are no specific timeframes required as to when the laboratory must begin completing alternative assessments or proficiency testing. The laboratory is required to perform at least 2 alternative assessment per year of testing or enroll in external proficiency testing.

**2. Could you please talk more details how to perform wipe (environmental) testing? How often should it be performed?**

A wipe or swipe test can be done by:

- Dampening a sterile swab in sterile saline
- Swabbing the area around the testing instrument



- Testing the swab in the same manner as a patient test is performed.

A positive result from a wipe test indicates environmental contamination. You must thoroughly cleanse the area to eliminate the contamination.

The wipe test is a good tool for monitoring for contamination, especially if the laboratory is seeing a higher number of positive results than expected. Laboratories must have written procedures on how they will monitor for the presence of false positive results. In addition to wipe tests, the policy could also include the review of summary statistics (e.g. monitoring the percentage of positive results relative to current local and regional rates) and the investigations of physician inquires.

The frequency for performing wipe tests is left to the discretion of the laboratory director as this may vary depending on the laboratory's specific setting. If there is suspicion of contamination or previous contamination, you will want to monitor more frequently. For completely closed systems, contamination is typically less likely; however, there has been incidences of false positive results with closed systems also. In addition to monitoring, your laboratory should also use process controls to minimize the risk of contamination.

For more information, refer to the following checklist items as applicable to your laboratory: IMM.41900, LSV.45740, LSV.48475, MIC.63252, MOL.32440, POC.08675.

**3. If you are using three different platforms to perform molecular COVID-19 testing, do you need to do comparison testing between the platforms? If so, how often and with how many specimens?**

Instrument or method comparisons are required at least two times per year. The laboratory must establish the process and acceptability for such comparisons. The laboratory defines any requirements on the number of specimens to use. Additional information can be found under the All Common Checklist at COM.04250.

Laboratories often compare test results from different instruments or methods as part of the verification studies when they are introducing a new instrument or method. This data can be used as one of the events for COM.04250.

**Verification/Validation**

**1. Are there any requirements/restrictions with FDA EUA authorized assays if a laboratory wants to expand the testing to asymptomatic individuals (public/Athletes/Fundraisers)?**

At this time, most EUA-authorized COVID-19 diagnostic tests are authorized for use in individuals suspected of COVID-19 by their health care providers. Testing of asymptomatic individuals who are suspected of COVID-19 is at the discretion of the individual authorized under state law ordering the test. In some states, a patient may order a test. GEN.40930 requires laboratories to perform testing only at request of an authorized person.

Laboratories and manufacturers interested in developing and using tests intended for the broad screening of asymptomatic individuals should contact the FDA at CDRH-EUA-



Templates@fda.hhs.gov to discuss the validation necessary to support an EUA for such an indication.

**2. We plan to modify the specimen collection procedure for an EUA approved serology test. Does my laboratory need to submit a new EUA to the FDA? What kind of validation does my lab need to do?**

If there is any modification to the EUA or manufacturer's instructions for use (IFU) for a serology test, the laboratory is required to validate the modification (COM.40250), including evaluation of accuracy, precision, reportable range, analytical specificity and sensitivity as well as other performance characteristics.

It is optional for laboratories to submit an EUA for serology tests. Manufacturers must submit an EUA for serology tests, including changes to the EUA.

**3. I work at a provider-owned lab and normally we are only allowed to complete toxicology testing for our patients. How does the EUA ruling affect this? Are we able to perform COVID testing for the public?**

Laboratories subject to US regulations with a CLIA certificate appropriate for the complexity of testing to be performed may offer testing for COVID-19. The laboratory must also meet other requirements for the qualifications and training of testing personnel and supervisory personnel, ordering of tests, reporting of results, and other relevant checklist requirements. If the testing is intended for broad screening of asymptomatic patients, please refer to the FDA's Q&A section for additional information on developing broad screening of asymptomatic patients.

**4. What is required for verifying a molecular-based COVID-19 test prior to use?**

Laboratories using an unmodified EUA test kit must verify the test method performance specifications (accuracy, precision, reportable range, and reference intervals), as applicable at their own laboratory prior to beginning patient testing. The laboratory may use information published in the manufacturer's package insert and other published literature for some aspects of the study (e.g., interferences). While the ultimate objective is to fully verify the method performance of the assay, the pandemic crisis, urgent need for patient testing, and possible lack of reagents and supplies make it difficult to fully evaluate the accuracy, precision, and reportable range, as stated in COM.40300. A more limited approach may be acceptable. You and your laboratory director should determine the depth of verification needed to begin testing and your laboratory director (or designee meeting CAP director qualifications) must approve the verification study prior to testing (COM.40475).

The test kits may have quality control materials for checking performance of the test kit. For accuracy verification, laboratories may use known positive and negative patient specimens, positive and negative QC materials, and other commercially purchased materials. Patient specimens can be altered (e.g., spiked with control materials). The CAP encourages laboratories to continue to evaluate assay performance as testing continues and more positive specimens become available for verification studies.



**5. Has covid-19 testing been classified as a specific specialty, i.e. virology?**

COVID-19 testing has not been assigned a CLIA specialty or subspecialty at this time. The CMS has stated that it will inform laboratories once it has been assigned.

**6. Is a mid-turbinate swab acceptable for nasopharyngeal sample collection?**

The FDA has granted EUA to alternate collection sites as nasopharyngeal swabs were at a high demand with shortages. Please review the testing/kit manufacturer's instructions for use to determine if they have already given alternate collection sites.

**7. If we have developed an LDT are we required to submit it to the FDA for EUA?**

If the laboratory develops a molecular test for diagnosis, you are required to submit for an EUA to the FDA. Laboratories should submit if they are developing antibody testing to the FDA for EUA.

**8. If my laboratory has paused molecular testing, what do we need to do to bring it back on-line?**

When the laboratory is ready to resume testing, it must follow the steps described in COM.40805 (Intermittent or Seasonal Testing) to verify readiness for testing. If your laboratory previously removed activities from its activity menu, log into cap.org and update your activity menu in Organization Profile.

**9. Is an inactivation step necessary for serum samples for SARS-CoV-2 antibody testing? If so, what is the inactivation process?**

The laboratory must follow the manufacturer's instructions for use for the EUA serology test. Not all testing may have this as a required step. For a laboratory-developed test, this would need to be evaluated when developing the method.

**10. If there are only approximately 300 labs performing serological testing, what action is being taken for proper diagnosis? Is there a high risk for false results?**

Serologic testing is not used for diagnosis. Serologic testing is to be used only for:

- Providing data for seroprevalence of SARS-CoV2 infection and epidemiologic studies
- Identification of individuals that have been infected in the past
- Identification of potential convalescent plasma donors
- Monitoring immune response during vaccine clinical trials

As more and more serology tests are being authorized by the FDA, the CAP expects the number of laboratories performing serology testing to increase.



**11. For swab and media changes, do we need to validate each new swab manufacturer or media manufacturer?**

The FDA has granted EUA to alternate collection devices as well as media. If the laboratory is switching to another collection device or media that is not on the EUA list, a bridging study comparing them will be necessary.

**12. Do we need to add the EUA tests to our activity menu?**

Yes, your laboratory's activity menu must include all testing performed by your laboratory, including EUA COVID-19 testing. The Master activity Menu includes activities for the assays listed below.

Molecular-based assays:

nCOV 2019, NAA, EUA, nonwaived  
nCOV 2019, NAA, EUA, LDT  
nCOV 2019, NAA, EUA, waived  
nCOV 2019, NAA, EUA, waived, POCT

Antigen assays:

SARS (CoV) antigen, EUA, waived  
SARS (CoV) antigen, EUA, waived, POC

Serology assays:

nCOV 2019 antibodies  
nCOV 2019 antibodies, rapid test, POCT

**General Questions:**

**1. Can a CAP inspection be performed virtually?**

The CAP recently announced its plans to resume US routine inspections. The health and safety of laboratorians and inspectors is of the utmost importance to the CAP. You can read more about it at <https://www.cap.org/laboratory-improvement/news-and-updates/cap-resumes-us-routine-inspections>.

The CAP is unable to complete the full CAP inspection virtually but is planning to incorporate some provisions that will allow some documents to be reviewed electronically prior to the inspection. Other actions, such as having announced inspections and using smaller inspection teams for the on-site inspection will also be implemented for inspections occurring during the pandemic.



- 2. We report positive sample results to our state agency whether the sample is received from within the state our lab is located or outside. Who is responsible for reporting positive results of samples received from states outside of our state to that specific state?**

The Department of Health and Human Services recently announced a new guideline for reporting of COVID-19 test results to state and local public health departments that includes specific instructions and data elements that must be reported. The guideline specifies that results must be reported to the state or local public health department based on the individual's residence. For more information, please review the HHS guidance at:

<https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>.

- 3. Could you please say something more about CAP accreditation with respect to workplace/employer testing?**

CAP-accreditation is intended for testing performed for the diagnosis, prevention, treatment of any disease or impairment of, or the assessment of the health of, human beings. Workplace testing for other purposes, such as to determine an individual's eligibility to work based on COVID-19 antibody status, is not subject to CAP inspection.

- 4. Is board-certification in microbiology required to sign off/review COVID tests covered under EUA??**

Signout can be done by pathologists or doctoral level individuals boarded in disciplines recognized by CMS.