

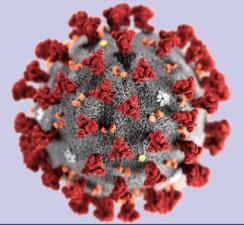
CLIA CORNER

State Hygienic Laboratory at The University of Iowa

Third Quarter 2023

In This Issue...

- The Public Health Emergency for COVID has ended- what does that mean for laboratory testing?



During the Public Health Emergency (PHE), the Centers for Medicare and Medicaid Services (CMS) exercised enforcement discretion and used other flexibility to aid laboratories in performing laboratory testing. Now that the PHE has been declared over, what does that mean for laboratory testing?

Is my laboratory still required to report positive and negative SARS-CoV-2 results to state public health departments?

CMS had the authority to require the reporting of positive and negative COVID results to state public health departments during the PHE. The CLIA requirement that all certificate types report SARS-CoV-2 test results ended with the termination of the PHE on May 11, 2023. Under the CLIA regulations, facilities performing SARS-CoV-2 testing are no longer required to report positive and negative results to state public health departments. CLIA will no longer perform surveys related to SARS-CoV-2 test reporting. However, there may be additional reporting requirements that are not enforced by CMS that could continue to require the reporting of SARS-CoV-2 test results (e.g. state reporting requirements or accrediting agency requirements). Laboratories should verify all current guidance before discontinuing the reporting of test results.



Will CMS continue to allow the testing of asymptomatic patients for molecular and antigen point of care testing?

On December 7, 2020, CMS issued guidance explaining that it would temporarily allow laboratories to use FDA-authorized SARS-CoV-2 molecular and antigen Point of Care (POC) tests on asymptomatic individuals, which is outside of the test's authorization. The FDA has authorized numerous antigen and molecular tests, as well as a number of over-the-counter tests that are intended for use in asymptomatic individuals. ***Now that the PHE has expired, all CLIA-certified laboratories are required to follow the manufacturer's Instructions for Use (IFU), including the intended use, for SARS-CoV-2 testing.***

If you would like your name added to our CLIA Corner Google Group, send an email to:

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Under the CLIA regulations, if a test's intended use is modified from what is required by the IFU, it is considered a high complexity test system. For modified test systems, laboratories must establish the performance specifications of accuracy, precision, analytical sensitivity, analytical specificity, reportable range, and reference range. Additionally, all individuals performing the testing must meet the CLIA requirements for high complexity testing personnel. CLIA will not consider it a modification, however, if the IFU states that the test's intended use is for "individuals suspected of COVID-19 by their healthcare provider" and the laboratory uses the test on asymptomatic individuals. Whether or not a patient is suspected of having COVID-19 is a healthcare provider's decision. In addition, it is the healthcare provider's responsibility, not the laboratory's, to ensure that subsequent testing, e.g., serial testing, required by the IFU is performed. This is a return to pre-PHE regulatory requirements.



Will CMS continue to allow alternate specimen collection devices now that the PHE has expired?

CMS will no longer allow alternate specimen collection devices. This flexibility ended when the PHE expired. CLIA regulations do not list specific specimen collection devices or viral transport media that laboratories must use to perform a test. CLIA only requires that the laboratory follow the manufacturer's instructions. If the manufacturer's instructions list a specific collection swab or specific brand of transport media, then those items must be used by the laboratory. Using a different specimen collection swab or transport media is testing outside of the IFU and makes the test system highly complex. The laboratory will need to establish the performance specifications of accuracy, precision, analytical sensitivity, analytical specificity, reportable range, and reference range when using alternate collection devices or transport media, and all laboratory personnel will need to meet the high complexity testing requirements.



Now that the PHE has expired, will laboratories be allowed to use expired reagents?

CMS has determined that laboratories will no longer be able to use expired reagents due to COVID-19 reagent supply problems. Under CLIA regulations, laboratories cannot use expired reagents (see 42 CFR § 493.1252(d)).

If my laboratory previously verified an EUA test for the detection of SARS-CoV-2, will the laboratory need to re-verify the test once the manufacturer receives FDA clearance/approval of that test?

As long as the EUA and cleared/approved products are the same from an intended use, design, chemistry, sample processing, consumables and procedures standpoint, and as long as the manufacturer's instructions regarding performance verification remain the same, the laboratory does not need to re-verify the test once the manufacturer receives FDA clearance/approval of that test.



Now that the PHE is over, how soon can a facility start testing once they have sent the CMS-116 application to the State Agency?

During the PHE, CMS expedited CLIA application (CMS-116) review and processing. CMS allowed laboratories to begin testing prior to paying the applicable laboratory fees to ensure that there was not a delay in COVID-19 testing. Now that the PHE has ended, CMS will no longer expedite the CLIA application review and processing for laboratories wishing to perform COVID-19 testing. Laboratories may only begin testing after the application is processed, payment has been posted to the CMS database, and the facility receives the new CLIA number or new CLIA certificate.

Generally, the CLIA application process takes 6-8 weeks. Laboratories should plan ahead to ensure certificates are received prior to performing patient testing. CMS has recently started issuing electronic certificates, which will speed up the process. To receive an electronic certificate, the facility will need to provide an email address and check the box, "Receive Future Notifications Via Email" on the CMS-116 application.



Laboratories with a Certificate of Waiver (CoW) were eligible to perform testing for COVID-19 using tests authorized by the Food and Drug Administration (FDA) for use in CoW settings during the PHE. Can these facilities continue to use these test kits?



Laboratories with a Certificate of Waiver (CoW) will continue to be eligible to perform testing for as long as the test's Emergency Use Authorization remains in effect. Once the assay has gone through the FDA's full traditional marketing authorization, it will receive CLIA complexity categorization. If the test remains categorized as waived, no further action would be necessary. ***If the FDA categorizes the test as moderate or high complexity, the test cannot be performed with a CLIA CoW.*** The laboratory director is responsible for either discontinuing the use of the test, or applying for a Certificate of Compliance or Certificate of Accreditation and meeting the non-waived CLIA requirements for performing moderate/high complexity testing should they choose to continue using the test. Test complexity (waived, moderate, or high) categorization for all FDA approved tests can be found on the [FDA CLIA Complexity Database](#).

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Will proficiency testing (PT) be required for SARS-CoV-2 testing after the PHE has ended?

The majority of SARS-CoV-2 testing has been categorized under the subspecialty of virology. PT is required for the subspecialty of virology. This would include both antigen and molecular testing for SARS-COV-2. The analyte specialty can be confirmed for all FDA approved test systems on the [FDA CLIA Complexity Database](#).



Updates Regarding the Abbott iSTAT

As of 2/28/2020 and 4/9/2020, the Abbott iSTAT CHEM8+ (Blue) and the CG4+ (Blue) cartridges were cleared by the FDA and categorized as moderate complexity testing for arterial or venous whole blood. This remains in effect even though the PHE expired.

The G3+ (Blue) test cartridge has not been cleared by the FDA as a moderate complexity test. During the PHE, however, CMS allowed laboratories with a Certificate of Registration that applied for a Certificate of Compliance, or laboratories with a Certificate of Compliance that had the i-STAT system, to use the G3+ (BLUE) test cartridge as a moderate complexity test. ***This enforcement discretion ended when the PHE expired.*** Since the G3+ (Blue) test cartridge has not been cleared by the FDA, this makes the use of that cartridge equivalent to high complexity testing. Laboratories must establish the performance specifications of accuracy, precision, analytical sensitivity, analytical specificity, reportable range, and reference range. Additionally, all individuals performing the testing must meet the CLIA requirements for high complexity testing personnel.

CMS will continue to allow laboratories with a Certificate of Registration that applied for a Certificate of Compliance, or laboratories with a Certificate of Compliance that have the i-STAT system to use the Troponin (cTnI) test cartridge as a moderate complexity test until such time that the FDA categorizes troponin testing and posts the categorization on their website. Laboratories using the cTnI test cartridge need to follow all CLIA regulations that apply to moderate complexity testing.

Please note: Laboratories with a Certificate of Accreditation (CoA) are advised to contact their Accreditation Organization (AO) for specific guidance about the use of G3+ (BLUE) and cTnI test cartridges, as the AO may have more stringent requirements than those listed above.

Abbott Point of Care Inc., i-STAT 1 System {i-STAT BLUE CG4+ Cartridge}

CR200106	K200492	Lactic acid (lactate)	General Chemistry	MODERATE	04/09/2020
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Abbott Point of Care Inc., i-STAT 1 System {i-STAT BLUE CG4+ Cartridge}

CR200106	K200492	pH	General Chemistry	MODERATE	04/09/2020
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Abbott Point of Care Inc., i-STAT 1 System {i-STAT BLUE CG4+ Cartridge}

CR200106	K200492	PCO2	General Chemistry	MODERATE	04/09/2020
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Abbott Point of Care Inc., i-STAT 1 System {i-STAT BLUE CG4+ Cartridge}

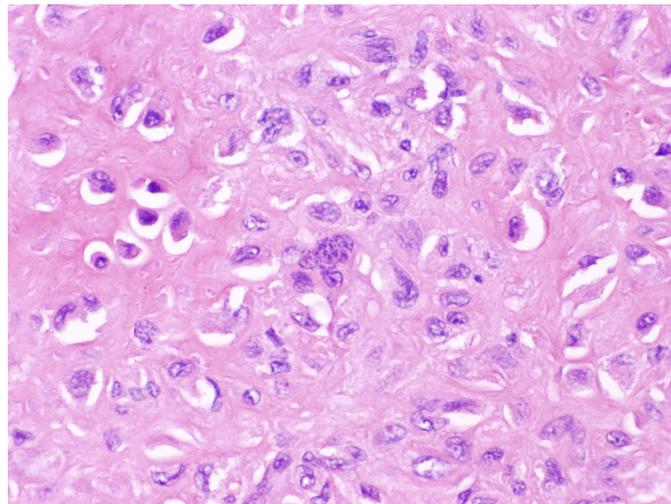
CR200106	K200492	PO2	General Chemistry	MODERATE	04/09/2020
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During the PHE CMS allowed for pathologists to review pathology slides remotely. Are the reading of digital images slides still acceptable?

CMS will continue to allow pathologists and other laboratory personnel to review digital laboratory data, digital results, and digital images remotely without obtaining a separate CLIA certificate for the remote site. This may be done as long as the designated primary site or home base has a certificate and the work being performed at the remote testing site falls within the specialties/subspecialties under the primary site's certificate. For example, a dermatology office is marked for the subspecialty of histopathology for the reading of biopsy slides. The qualified testing personnel are allowed to interpret digital biopsy images at a remote site. However, they would not be able to interpret abnormal peripheral blood smears at the remote site, because the primary dermatology office is not approved for the specialty of hematology.



A private residence can be considered a remote testing site. CMS considers digital data, results, and images accessed by VPN or other secure method to be an extension of the laboratory that does not require a microscope or other laboratory equipment. Therefore, since the remote site does not use traditional laboratory equipment like a microscope, a separate CLIA certificate is not needed. However, when physical slides are reviewed remotely, a separate CLIA certificate is required. The separate CLIA certificate is needed to provide oversight of the equipment needed to read slides. Without oversight, there is potential for inaccurate laboratory results. In addition, physically transferring slides from one site to another also adds a potential increased risk of error. ***CMS will allow the review of digital images, but not the review of physical slides at a remote location.***



Laboratories that choose to allow staff to remotely review digital laboratory data, digital results, and digital images may only do so when the following criteria are met:

- The primary, home site, laboratory has a current, unrevoked or unsuspended certificate of waiver, registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory (42 C.F.R. § 493.3(a)(1)).
- The primary laboratory complies with other applicable federal laws, including HIPAA.
- The laboratory director of the primary site CLIA number is responsible for all testing performed under its CLIA certificate, including testing and reporting performed remotely.
- Survey findings will be cited under the primary laboratory's CLIA certificate. Enforcement actions, if taken, will affect the primary laboratory's CLIA certificate.
- The primary laboratory's test reports must indicate the remote site location where the testing is performed. The laboratory may use a coding system rather than the remote site address, e.g., personnel residence, on the final report. This coding system must be available upon request.
- The primary laboratory must be certified in the specialties and/or subspecialties of the work performed at the remote site.
- The primary laboratory must provide CMS a list of all staff working remotely, upon request.
- The primary location is responsible for retaining all documentation, including testing performed by staff working remotely.
- The individual performing remote review must be on the primary laboratory's Form CMS-209, Laboratory Personnel Report (CLIA).

**All information in this CLIA Corner came from the
CMS memo QSO-23-15-CLIA.**