

CLIA FAQs: Post-PHE Guidance

1. Will my laboratory still be required to report SARS-CoV-2 test results after the PHE is declared over by the HHS Secretary?

Response: No. The authority to require reporting of SARS-CoV-2 test results is linked to the PHE declaration. The CLIA requirement for all certificate types to report SARS-CoV-2 test results will expire with the termination of the PHE, May 11, 2023. However, there may be additional reporting requirements, e.g., state requirements, not enforced by CMS that may continue to require reporting. Laboratories should verify all current guidance, before discontinuing reporting of test results.

2. Will CMS continue to survey for SARS-CoV-2 test results reporting after the PHE has ended?

Response: No. Once the PHE is terminated, CLIA will stop performing surveys related to SARS-CoV-2 test result reporting. However, laboratories must retain records of testing in accordance with [42 CFR 493.1105](#).

3. Will the enforcement discretion for staff reviewing digital clinical laboratory data, digital results and digital images remotely continue after the PHE is declared over by the HHS Secretary?

Response: Yes. CMS will continue the enforcement discretion allowing staff to review of digital clinical laboratory data, digital results and digital images, remotely as long as the criteria in QSO-23-15-CLIA are met. Primary laboratory test reports must indicate the name and address where the testing is performed. However, in the case of a private residence, the laboratory may use a coding system rather than the home address on the final report. This coding system must be available upon request.

4. Will the enforcement discretion for remote examination of physical slides continue after the PHE is declared over by the HHS Secretary?

Response: No. Physical slides being examined using a microscope which are not digital images, cannot be read remotely under a primary location CLIA certificate as described above. Slides must be read at a CLIA-certified laboratory primary location. All applicable CLIA requirements must be met.

Test reports must indicate the name and address where the testing is performed. However, in the case of a private residence, the laboratory may use a coding system rather than the home address on the final report. This coding system must be available upon request.

5. I have been performing remote review of clinical laboratory data, results, physical slides, and digital images during the PHE without a separate CLIA certificate. Can I continue this practice after the PHE is no longer in effect?

Response: We will continue to exercise enforcement discretion to ensure pathologists and other laboratory personnel may review **digital laboratory data, digital results and digital images** remotely. We will not enforce the requirement to have a separate certificate for laboratories that are located at a remote testing site, provided that the designated primary site or home base has such a certificate (using the address of the primary site) and the work being performed in the remote testing site falls within the specialties/subspecialties under the primary site's certificate. A private residence may be a remote testing site. Please note that the CLIA statute and regulations for cytology state that cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology (42

U.S.C 263a(f)(4)(B)(vi), 42 C.F.R. 493.1274(a)). Remote review of cytology digital images is included in this enforcement discretion. See Question 3.

However, **physical slides, including pathology**, being examined using a microscope that are not a digital image, cannot be read remotely under a primary location CLIA certificate as described above. Slides must be read at a primary site CLIA-certified laboratory.

6. If I am reviewing patient digital images and digital data remotely, can I perform proficiency testing (PT) in the same way?

Response: Yes. As long as the remote site is operating under a primary site CLIA number, CMS would not consider the review of PT digital data to be a PT referral since all parties were acting under a single CLIA number.

7. Does enforcement discretion apply to PT for cytology gynecologic examinations (Pap smears)?

Response: No. Cytology gynecologic proficiency testing (PT) involves reading physical slides so this enforcement discretion does not apply. Laboratories performing testing under the specialty of Cytology, must follow the CMS-approved Cytology gynecologic PT program requirements and guidelines. All Cytology PT slide reviews must occur at the primary site, under the direction of a proctor and not at different site.

8. Does this guidance apply to laboratory personnel who have already obtained CLIA certificates for their home or other sites separate from the primary testing site?

Response: No, this guidance regarding remote sites does not apply to pathologists who have already obtained a CLIA certificate, and are not operating under any other CLIA certificate. Laboratory personnel who have obtained a CLIA certificate for the remote testing site may decide not to renew their CLIA certificate; and instead, perform remote review of clinical laboratory data, results and digital images for a primary site, as long as the criteria in QSO-23-15-CLIA are met.

9. Will the enforcement discretion for using molecular and antigen SARS-CoV-2 tests for asymptomatic individuals continue after the PHE is declared over by the Secretary?

Response: No. 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. As of the publication date of this memorandum, all CLIA-certified laboratories are required to follow the manufacturer's Instructions for Use (IFU), including the intended use, for SARS-CoV-2 testing. Under the CLIA regulations, modifications to a test's IFU means the test is high complexity. However, we would not consider it a modification of the IFU when the IFU states, for example, "individuals suspected of COVID-19 by their healthcare provider", and the test is ordered by the healthcare provider for asymptomatic patients. The decision if an individual is suspected of COVID-19 is made by the healthcare provider. If a laboratory accepts referral specimens, written instructions for specimen submission and handling must be available to the laboratory's clients, including specimen acceptability and rejection criteria.

If a test is modified, the laboratory must establish performance specifications as required at §493.1253(b)(2) and meet high complexity personnel requirements in §§493.1441-1489. The laboratory director is responsible for ensuring that the procedures used to establish performance specifications are adequate to determine the method's accuracy, precision, and other pertinent performance characteristics and that the test method can provide quality results. This is a return to pre-PHE regulatory requirements.

Finally, it is the responsibility of the healthcare provider, not the laboratory, to ensure that subsequent testing, such as serial testing, stated in the IFU is performed.

During the PHE, laboratories were temporarily allowed to use FDA-authorized SARS-CoV-2 molecular and antigen Point of Care (POC) tests on asymptomatic individuals, which were outside of the test's authorization. As of the end of the PHE, all CLIA-certified laboratories are required to follow the manufacturer's Instructions for Use (IFU), including the intended use, for SARS-CoV-2 testing. Under the CLIA regulations, if a test's intended use is modified from what is required by the IFU, the test becomes high complexity and laboratories must establish performance specifications and have qualified personnel. However, many of the POC facilities have Certificates of Waiver, and would be challenged to meet these requirements. In the case of POC molecular and antigen tests, the IFU states the test is intended for "individuals suspected of COVID-19 by their healthcare provider." In order to mitigate these laboratories needing to meet high complexity requirements, CMS (CLIA) will not consider it a modification of the IFU when the IFU includes this statement and when these tests are used on asymptomatic patients. This allowance, in addition to the numerous antigen, molecular, and over-the-counter tests authorized by the FDA that are intended for testing asymptomatic individuals, will ensure the availability of COVID-19 tests. Laboratories can continue to use these tests. Whether a patient is suspected of having COVID-19 is a healthcare provider's responsibility to determine. Please note that laboratories should refer to FDA's EUA for the Conditions of Authorization on authorized COVID-19 tests.

10. Will CMS continue to use the remote survey process after the PHE is over?

Response: No. All CLIA surveys, including those performed by accreditation organizations, will be performed onsite.

11. 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 public health emergency (PHE). Can these facilities continue to use these test kits?

Response: Refer to the [FAQs on Testing for SARS-CoV-2](#). 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 FDA would notify the public via their [FDA CLIA Complexity Database](#). 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 meet the requirements to perform moderate/high complexity testing should they choose to continue using the test. For example, if a test is categorized by the FDA as moderate complexity, laboratories with a CoW cannot perform the test.

12. How will States, Locations and CMS partners be notified of possible changes in complexity of tests that were EUAs under the PHE?

Response: If the FDA categorizes the test as waived, moderate or high complexity, the FDA would notify the public via their website, [FDA CLIA Complexity Database](#).

13. What happens if a surveyor finds that a laboratory did not participate in proficiency testing for analytes in Subpart I during the COVID-19 PHE?

Response: The surveyor will determine whether patient testing was performed during the timeframe of the PT event and whether or not the laboratory contacted the PT program to be excused. Generally, if the laboratory was reporting patient results but did not participate in a PT event for that analyte, it would be cited accordingly. However, the SA and CMS may grant an exception in accordance with Chapter 6 of the State Operations Manual at section 6056 depending on the circumstances.

14. Has SARS-CoV-2 been assigned a specialty by the FDA?

Response: The FDA has categorized several tests under the subspecialty of virology. The specialty/subspecialty information can be found on the [FDA CLIA Complexity Database](#) in the “Analyte Specialty” column.

Document	Parent	Analyte	Analyte Specialty	Complexity	Effective Date
			Virology		
			Virology		

15. Will PT be required for SARS-CoV-2 testing after the PHE has ended?

Response: PT is required for the subspecialty of virology in laboratories that perform viral antigens or test for viral structures. This would include both antigen and molecular testing for tests that the FDA has determined fall under the subspecialty of virology. Laboratories will need to enroll in PT, if PT is available.

16. Can a laboratory use expired reagents after the PHE is declared over?

Response: Laboratories cannot use expired reagents per the regulatory requirements at 42 CFR 493.1252(d). The use of expired reagents would be considered a modification and require establishment of performance specifications for a modified procedure. This is a return to pre-PHE regulatory requirements.

17. Can my laboratory continue to use alternative specimen collection devices after the PHE?

Response: CLIA regulations are not prescriptive about the type of transport device, for example, specimen collection swabs and viral transport media that laboratories use to collect the specimens needed to perform a test. CLIA only requires that the laboratory follow the manufacturer’s instructions. If the alternate specimen collection device or media is not specified in the manufacturer’s instructions, the laboratory must establish performance specifications prior to reporting patient test results. CLIA is not prescriptive as to how the establishment of performance specifications study is performed; the laboratory director is responsible for ensuring that establishment of performance specifications meets regulatory requirements. This is a return to pre-PHE regulatory requirements.

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

Response: 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

instruction 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.

19. If an authorized EUA sample type is removed from the sample types listed in FDA-cleared/approved SARS-CoV-2 test, and if the laboratory previously verified those removed sample types on the EUA test, would a laboratory need to establish performance specifications on the FDA-cleared/approved test, since those sample types are now considered a modification of the IFU?

Response: For modified FDA-cleared or approved test systems, the CLIA requirements state that laboratories must establish certain parameters per section [493.1253\(b\)\(2\)](#). The establishment of performance specifications must include Accuracy, Precision, Analytical sensitivity, Analytical specificity, Reportable range, Reference intervals, and any other performance characteristics required for test performance. A sample type not listed in the FDA-cleared test system would be a modification, and require establishment of performance specifications. The laboratory director must ensure that the procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. See Question 16.

Please note that the CLIA requirements are minimum requirements. Some states may be more stringent than CLIA and have state laws regarding patient testing, and two states, New York and Washington, have exempt state status. You would need to contact each of the states you are interested in for their specific requirements. The State Agency (SA) where the laboratory is located ([State Agency Contacts](#)) can answer your questions related to state requirements.

In addition, laboratories with a Certificate of Accreditation (CoA) are advised to contact their Accreditation Organization (AO) for specific guidance, as the AO may have more stringent requirements. Helpful link: [AO Contacts](#)

20. Will electronic signatures be acceptable?

Response: As stated in [QSO-21-10-CLIA-REVISED](#), secure or digital electronic signatures are acceptable (e.g., Form CMS-116, PT attestation). The electronic signature should have an electronic date/time stamp. If electronic signatures are being used, the laboratory should show evidence that only the authorized person can utilize the electronic signature.