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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-23-15-CLIA

DATE: May 11, 2023

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Post-Public Health Emergency (PHE) Guidance

Memorandum Summary

- **CMS only has authority to require reporting of SARS-CoV-2 test results until the end of the Federal PHE declaration. As a result, the CLIA requirement for laboratories to report SARS-CoV-2 test results will expire with the termination of the PHE.**
- **CMS is clarifying the post-PHE status of the temporary exercise of enforcement discretion and other flexibilities CMS utilized during the COVID-19 PHE.**

Background

CMS has been committed to taking critical steps to ensure America's clinical laboratories could respond to the threat of COVID-19 to ensure patient health and safety. The intent of the CLIA program is to ensure that laboratory test results provided to individuals and their health care providers are accurate and reliable. During the Public Health Emergency (PHE) posed by COVID-19, there was an urgent need to expand laboratory capacity. In response, CMS exercised enforcement discretion and used other flexibilities to address this critical need.

During the PHE, CMS did not enforce certain CLIA regulations, provided that laboratories followed the specific parameters outlined in CLIA PHE guidance. CMS also relaxed or changed policies and procedures to provide more flexibility within the CLIA regulations and highlighted flexibilities that already existed.

The exercise of some of these enforcement discretions and broad flexibilities will be terminated by the end of the PHE, as they were intended to address the acute and extraordinary circumstances of a rapidly evolving pandemic and not replace existing requirements.

Discussion:

SARS-CoV-2 Test Result Reporting Requirements

Section 18115 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act[1] required "Every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 shall report the results from each such test, to the Secretary of Health and Human Services in such form and manner, and at such timing and frequency, as the Secretary may prescribe until the end of the Secretary's Public Health Emergency declaration with respect to COVID-19." Pursuant to this authority, CMS implemented regulations requiring laboratories to report SARS-CoV-2 test results during the PHE. Because CMS only has authority to require reporting during the PHE, the CLIA requirement that all certificate types report SARS-CoV-2 test results will end when the PHE is terminated on May 11, 2023. 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). Laboratories should verify all current guidance before discontinuing the reporting of test results.

Exercise of Enforcement Discretion and Other Flexibilities

This memorandum supersedes previous guidance published on the topics below.

CMS exercised certain enforcement discretions and flexibilities that, while useful during the initial response to COVID-19, are no longer needed. In determining whether to continue the exercise of these enforcement discretions and flexibilities, CMS considered impacts on the communities we serve, including underserved communities, and the potential barriers and opportunities the exercise of these enforcement discretions and flexibilities created. To ensure the accuracy, reliability, and timeliness of laboratory results, CMS has determined that it will no longer excuse noncompliance with certain CLIA regulatory requirements once the PHE has terminated.

Remote Staff Performing Review of Digital Clinical Laboratory Data, Digital Results and Digital Images

The CLIA regulations at 42 C.F.R. §§ 493.35(a), 493.43(a), and 493.55(a)(2) require laboratories to file a separate application for each laboratory location unless it meets a regulatory exception. Additionally, 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)).

To ensure the accuracy, reliability and timeliness of laboratory results, CMS will continue to exercise enforcement discretion to permit pathologists and other laboratory personnel to review digital laboratory data, digital results and digital images ("digital materials") remotely, without obtaining a separate CLIA certificate for the 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

[1] https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf

work being performed at the remote testing site falls within the specialties/subspecialties under the primary site's certificate. A private residence may be a remote testing site. We consider 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, the remote review of these materials does not require equipment that is essential to being a separate laboratory, while maintaining the accuracy, reliability, and timeliness of laboratory results.

However, when slides are reviewed remotely, a microscope and other laboratory equipment is necessary to perform the testing. The necessity of such equipment is a hallmark of a separate laboratory and, without heightened oversight, increases the potential for inaccurate laboratory results. In addition, physically transferring slides from one site to another constitutes a referral to another laboratory and involves increased risk of error. Therefore, after the PHE has terminated, CMS will not continue to exercise its enforcement discretion for the review of physical slides.

Laboratories that choose to allow staff to remotely review digital laboratory data, digital results and digital images may do so only if 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).

<u>Remote Staff Performing Examination of Physical Slides</u>

During the PHE, CLIA allowed all slides, including physical slides, to be reviewed remotely. Remote review of physical slides will no longer be allowed after the PHE ends. Physical slides, including pathology slides and cytology slides, being examined using a microscope that are not a digital image, cannot be read remotely under a primary location CLIA certificate as described

above. For example, if a pathologist, cytotechnologist, or medical laboratory scientist is reading slides at a site that is not the primary location, CLIA considers this secondary site a separate laboratory and requires that secondary site laboratory to have its own CLIA certification. The laboratories at the primary and secondary sites must meet all applicable CLIA requirements.

Under 42 C.F.R. § 493.1291(c), laboratory test reports must indicate the name and address of the laboratory location where the testing is performed. In the case of digital materials being reviewed at remote sites, for example, a private residence, the laboratory may use its own coding system, rather than the remote site home address, on the final report. This coding system must be available to CLIA upon request.

Expedited Review of CLIA Applications

During the PHE, CMS expedited CLIA certificate application review and processing by allowing laboratories to begin testing prior to paying the applicable laboratory fee to ensure that laboratories located in the United States wishing to perform COVID-19 testing were able to begin testing as quickly as possible during the PHE. Once the PHE ends, CMS has determined that it will no longer expedite CLIA certificate applications for laboratories performing COVID-19 testing. After the PHE, laboratories may only begin testing after they pay applicable laboratory fee(s) and receive a CLIA number or a CLIA certificate. This is a return to pre-PHE requirements.

Molecular and Antigen Point of Care Test Asymptomatic Testing

On December 7, 2020, CMS issued guidance explaining that it was temporarily allowing 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. 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 (§ 493.17(c)(4)). Laboratories must establish CLIA performance specifications as required at 42 C.F.R. § 493.1253(b)(2) and meet CLIA high complexity personnel requirements in 42 C.F.R. §§ 493.1441-1489 for all modified tests. 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 patients. Whether 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.

Laboratories Located at Contiguous Buildings on the Same Campus

CMS is clarifying here that CLIA regulations allow laboratories within a hospital/university hospital campus to hold a single certificate for the laboratory sites within the same physical location or street address, as long as the laboratories are under common direction, i.e., same

laboratory director. This requirement is expressly authorized under the CLIA regulations and does not constitute a use of enforcement discretion. (See 42 C.F.R. §§ 493.35(b)(3), 493.43(b)(3), 493.55(b)(3)).

Temporary Testing Sites

CMS is clarifying here that CLIA regulations allow laboratories that have multiple sites that are not at fixed locations, e.g., temporary testing sites, to have one CLIA certificate under the primary laboratory site or each temporary location can have a separate CLIA certificate. A temporary testing site is where an entity that is not at a fixed or permanent location performs laboratory testing. A temporary laboratory moves from testing site to testing site. If the temporary laboratory does not have its own CLIA certificate, it must be under a CLIA certificate in the name of the designated primary site or home base. Records, files, etc. for temporary testing sites may be kept at the primary site or home base. The personnel, equipment, supplies, and reagents, etc. are not kept at a temporary testing site on a permanent basis. Temporary testing sites may be off-site overflow locations, which may include schools, churches, or parking lots. The temporary site can only perform tests consistent with the primary site certificate, and would be under the direction of the primary site's existing laboratory director. This requirement is expressly authorized under the CLIA regulations and does not constitute a use of enforcement discretion. (See 42 CFR §§ 493.35(b)(1), 493.43(b)(1), 493.55(b)(1)).

Alternate Specimen Collection Devices

During the PHE, FDA permitted laboratories to use alternative transport media or viral transport media made using the CDC's posted recipe. In conjunction with this guidance, CLIA gave laboratory directors using these alterative transport mediums the discretion to decide if subsequent validation studies were needed before tests were performed. Once the PHE concludes, CLIA will no longer permit this flexibility.

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.

Once the PHE concludes, if the test manufacturer's instructions do not include instructions for using alternate specimen collection devices or media, the laboratory must establish test performance specifications using those alternative specimen collection devices or media prior to reporting patient test results. CLIA is not prescriptive about how laboratories establish test performance specifications; the laboratory director is responsible for ensuring that establishment of performance specifications meets regulatory requirements. See 42 C.F.R. § 493.1253(b)(2). This is a return to pre-PHE regulatory requirements.

Use of Expired Reagents

During the PHE, CMS allowed laboratories to use expired reagents due to COVID-19 reagent supply problems. CMS has determined that at the end of the PHE, laboratories will no longer be able to continue using expired reagents. Under CLIA regulations, laboratories cannot use expired

reagents (see 42 CFR § 493.1252(d)). Use of expired reagents would be considered a test modification and would require the laboratory to establish performance specifications for a

modified procedure. In addition, the test would default to high complexity. This is a return to pre-PHE regulatory requirements.

Abbott iSTAT

CHEM8+ (BLUE), CG4+ (BLUE), G3+ (BLUE)

- The CHEM8+ (BLUE) and the CG4+ (BLUE) cartridges were cleared by the FDA and categorized as moderate complexity for arterial or venous whole blood as of 2/28/2020 and 4/9/2020, respectively.
- G3+(BLUE) Test Cartridge: FDA has not cleared the G3+ cartridge 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 will end with the PHE.
- The G3+ (BLUE) cartridge analytes are included as analytes in the CG4+ (BLUE) cartridge, which is categorized by the FDA as moderate complexity.

Troponin (cTnI)

- 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 cTnI test cartridge as a moderate complexity test until such time that the FDA clears troponin 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.

Surveillance, University, Genetic Variant Testing

CLIA certification is required for laboratories that provide information for the diagnosis, prevention, treatment, or assessment of health, e.g., laboratories that report patient-specific results. See 42 C.F.R. §§ 493.2, 493.3(b)(2). However, during the PHE CMS temporarily exercised enforcement discretion under CLIA for SARS-CoV-2 surveillance testing where patient-specific results were generated but not reported to the individual (e.g., SARS-CoV-2 surveillance testing that does not utilize a pooling strategy). Neither CMS nor the State survey agencies cited non-CLIA certified facilities, such as university laboratories, that were performing such testing, provided that the facility did not report actual patient-specific test results to an individual, but only referred an individual with a presumptive positive or inconclusive test result to a CLIA-certified laboratory for further testing. Post PHE, all laboratories performing surveillance and genetic variant testing that report patient-specific results, including positive, negative, and inconclusive, are required to have a CLIA certification. This is a return to pre-PHE regulatory requirements.

Summary Table of Post-PHE Enforcement Discretions and Flexibilities

Enforcement Discretion (E), Flexibility (F)	(E) or (F)	Post-PHE Guidance
Remote Staff Performing Review of Digital Clinical Laboratory Data, Digital Results and Digital Images	E	This enforcement discretion will continue post-PHE. Pathologists and laboratory personnel will be allowed to review digital data, digital results and digital images remotely at a remote location under a primary location's CLIA certificate.
Remote Staff Performing Examination of Physical Slides, including Pathology	E	This enforcement discretion will not continue post-PHE. Pathologists, cytotechnologists, and medical laboratory scientists reading physical slides cannot do so remotely under a primary location CLIA certificate.
Expedited Review of CLIA Applications	F	This flexibility will not continue post-PHE. A laboratory must receive a CLIA number and pay the applicable laboratory fee(s) before testing begins.
Molecular and Antigen Point of Care Test Asymptomatic Testing	E	This enforcement discretion will not continue post-PHE.
Hospital Laboratories Located at Contiguous Buildings on the Same Campus	N/A	This was identified as a flexibility during the PHE but is allowed in the regulations.
Temporary Testing Sites	N/A	This was identified as a flexibility during the PHE but is allowed in the regulations.
Alternate Specimen Collection Devices	F	This flexibility will not continue post-PHE.
Use of Expired Reagents	E	This enforcement discretion will not continue post-PHE.
Abbott iSTAT, G3+	E	This enforcement discretion will not continue post-PHE for G3+.
Abbott iSTAT, Troponin	E	This enforcement discretion will continue post-PHE, but will not be tied to the PHE.
Surveillance, University, Genetic Variant Testing	E	This enforcement discretion will not continue post-PHE.

Contact:
For questions or concerns relating to this memorandum, please contact LabExcellence@cms.hhs.gov.

Effective Date:
Immediately. Please communicate to all appropriate staff within 30 days.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Attachment – Frequently Asked Questions (FAQ)

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 useto 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.

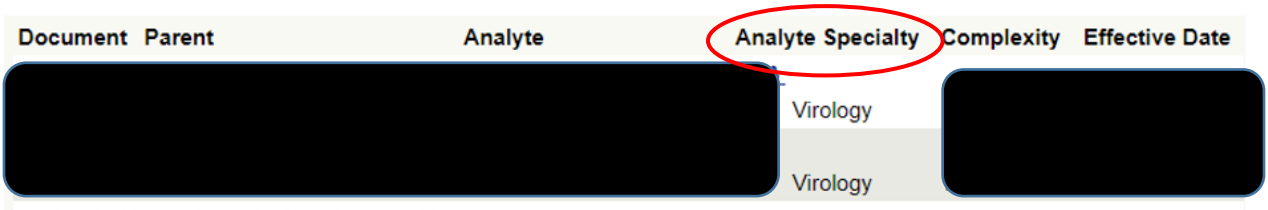
11. **Laboratories with a Certificate of Waiver (CoW) were eligible to perform testing for COVID-19 using tests authorized by the Food and Drug Administration (FDA) for use in CoW settings during the public health emergency (PHE). Can these facilities continue to use these test kits?**
Response: Refer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



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.