



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-20-21-CLIA

DATE: March 26, 2020

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance
During COVID-19 Public Health Emergency

Memorandum Summary

- CMS is issuing this memorandum to laboratory surveyors to provide important guidance to surveyors and laboratories during the COVID-19 public health emergency, such as:
 - CMS' Exercise of enforcement discretion to ensure pathologists may review pathology slides remotely if curtailed defined conditions are met ,
 - Ensuring that laboratories located in the United States wishing to perform COVID-19 testing that apply for CLIA certification are able to begin testing as quickly as possible during the public health emergency,
 - Highlighting that laboratories within a hospital/University Hospital Campus may hold a single certificate for the laboratory sites within the same physical location or street address,
 - Offering enforcement discretion as to Proficiency Testing (PT) During the duration of the Public Health Emergency,
 - Addressing alternate Specimen Collection Devices, and
 - Addressing Laboratory Developed Tests
- *CMS is committed* to taking critical steps to ensure America's clinical laboratories are prepared to respond to the threat of 2019 Novel Coronavirus (COVID-19) and other respiratory illnesses to ensure reliable testing as well as ensuring patient health and safety.
- All guidance in this memorandum is applicable only during the COVID-19 public health emergency.
- Laboratories that are accredited must follow their accrediting organization (AO) requirements and must follow applicable State laws, which may be more stringent than the CLIA requirements.
- The CLIA program is unable to approve section 1135 waiver requests with respect to waivers of CLIA program requirements. The section 1135 waiver authority is only applicable to specified programs (or penalties) authorized by the Social Security Act (SSA). The CLIA program does not fall into this category of programs.

Background

CMS is committed to taking critical steps to ensure America's clinical laboratories can respond to the threat of the COVID-19 and other respiratory illnesses to ensure patient health and safety. The intent of the CLIA program is to ensure that test results provided to individuals and their health care providers are accurate and reliable. During this state of emergency, CMS's inspection efforts are focused primarily on addressing immediate jeopardy situations, and CMS is generally exercising enforcement discretion for activities that do not rise to that level.

CMS issues this memorandum to provide important guidance for CLIA laboratories regarding the review of pathology slides, proficiency testing, alternate collection devices, and requirements for a CLIA certificate during the COVID-19 public health emergency. All guidance in this memorandum is applicable only during the COVID-19 public health emergency. Laboratories that are accredited must follow AO requirements. All laboratories need to also follow any State laws governing laboratories, which may be more stringent than CLIA.

The CLIA program is unable to approve section 1135 waiver requests with respect to waivers of CLIA program requirements. The section 1135 waiver authority is only applicable to specified programs (or penalties) authorized by the Social Security Act (SSA). The CLIA program does not fall into this category of programs. However, CMS is exercising our enforcement discretion during the current public health emergency.

Due to the public health emergency posed by COVID-19 and the urgent need to expand laboratory capacity, CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with laboratories located at temporary testing sites under the conditions outlined herein. We therefore believe that this guidance is a statement of agency policy not subject to the notice and comment requirements of the Administrative Procedure Act (APA). 5 U.S.C. § 553(b)(A).

For the same reasons explained above, the Administrator additionally finds that, even if this guidance were subject to the public participation provisions of the APA, prior notice and comment for this guidance is impracticable, and there is good cause to issue this guidance without prior public comment and without a delayed effective date. 5 U.S.C. § 553(b)(B) & (d)(3).

Discussion

Remote Review of Clinical Laboratory Data, Results and Pathology Slides

Recognizing the urgency of the public health emergency and the need to promote innovative uses of technology to increase capacity in order to avoid exposure risks to health care providers, patients, and the community, we are exercising enforcement discretion to ensure pathologists may review pathology slides remotely. The CLIA 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 C.F.R. 493.1274(a)). However, as we have done in previous public health emergencies, we are exercising our enforcement discretion and we will not enforce the requirement to have a separate certificate for laboratories that are located at a temporary 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 temporary testing site falls

within the parameters of the primary site's certificate. (§493.35(b)(1). 43(b)(1), 55(b)(1)) A temporary testing site is where, at various intervals of time, an entity that is not at a fixed or permanent location performs laboratory testing. Such a temporary testing site may be the pathologist's home.

Laboratories that choose to utilize temporary testing sites (e.g., for remote review and reporting of slides/images), may do so if the following criteria are met:

- 493.3(a) Basic rule. Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it—
 - (1) 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; or
- Per the regulations at 42 CFR §493.1105(a)(7) Slides. Cytology slide preparations must be retained for at least 5 years from the date of examination; Histopathology slides must be retained for at least 10 years from the date of examination; Pathology specimen blocks must be retained for at least 2 years from the date of examination; and Remnants of tissue for pathology examination must be preserved until a diagnosis is made on the specimen.
- Equipment, supplies, and reagents, and other similar items needed at the temporary site are not kept at a temporary testing site on a permanent basis.
- The temporary site complies with other applicable Federal law, including HIPAA.
- As per §493.1251 The primary site must have a written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. The Laboratory Director is not required to send but CMS may ask to inspect it in the future.

It is important to note that this guidance does not apply to pathologists who have already obtained CLIA certificates for their home or other sites separate from the primary testing site..

Expedited Review of CLIA Applications

Laboratories need a CLIA certificate to perform COVID-19 testing. Under CLIA, laboratories are prohibited from testing human specimens for the purpose of diagnosis, prevention, treatment, or health assessment without a valid CLIA certificate. To become CLIA-certified, laboratories must comply with the accuracy, quality, and reliability requirements as dictated by the statute. The purpose of these requirements is to ensure that the information that patients or their health care providers receive from a clinical laboratory is accurate and reliable test results. Laboratories that wish to become CLIA certified must apply for a CLIA Certificate.¹

We want to ensure that laboratories located in the United States wishing to perform COVID-19 testing that are applying for a CLIA certificate are able to begin testing as quickly as possible during the public health emergency. Therefore we have reviewed our regulations (42 CFR part

¹ https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.

493) and our procedures to expedite review of applications for a CLIA certificate. No requirements are being waived, However, once the laboratory has identified a qualified laboratory director and has provided all required information on the CMS-116 application, a CLIA number will be assigned. We are allowing for testing once a CLIA number has been assigned as opposed to laboratories waiting for a hard copy paper certificate to come in the mail. Once the CLIA number has been assigned, the laboratory can begin testing as long as applicable CLIA requirements have been met (e.g., establishing performance specifications).

Laboratories Located at Contiguous Buildings on the Same Campus

Laboratories within a hospital/University Hospital Campus that are located at contiguous buildings on the same campus and under common direction (meaning that all testing sites are under one designated director) may hold a single certificate for the laboratory sites within the same physical location or street address (42 CFR 493.35(b), 43(b), 55(b)). The street address may be different from the mailing address, which can be a Post Office box or a billing address. For large hospitals, such as a university campus facility, that may contain laboratories in separate buildings, consult the appropriate CMS location to determine if the hospital is eligible for a single certificate.

Proficiency Testing (PT) During a Public Health Emergency

- In the event that a PT Provider would need to postpone, suspend, or cancel, a proficiency testing event during the public health emergency:
 - The PT Provider must immediately notify CMS, Accreditation Organizations, Exempt States, and participating laboratories. PT provider should submit a plan to resume testing in a timely manner after the public health emergency to CMS.
 - Laboratories will not be penalized for lack of PT results if an event is postponed, suspended, or canceled, so long as the cancellation is documented (including the notification from the PT program), and PT is conducted in a timely manner after the public health emergency ends. However, labs should consider performing their own self-assessment to ensure reliable testing.
 - **Only CMS may allow postponement, suspension, or cancellation of CLIA-required PT activities while patient testing continues.** A PT program may not permit a laboratory to opt out of participating in a PT event while continuing to test patient specimens for reasons such as emerging public health outbreaks like seasonal influenza epidemic, unless CMS has granted it permission to do so.
 - Should CMS determine that PT should be postponed, suspended, or canceled, CMS will authorize the PT programs to use reason code 10.²
- In the event where a laboratory temporarily suspends performing a specific test due to staffing shortage, supply shortage, or reagent shortage:
 - The laboratory must document the timeframe during which the test is not being performed, and the reason therefore.
 - The laboratory must notify the inspecting agency and PT program within the timeframe of submitting PT results that it has ceased testing, and the reason therefore.

² PT Exception Code 10 = Excused Participation - Natural Disaster/Emergency.

- If the laboratory is still performing, or resumes such testing, and providing patient results, PT is still required and must be performed, as required by the CLIA regulations.

Alternate Specimen Collection Devices

During this public health emergency, with the exceptions outlined in this memo, CLIA regulations remain applicable. 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 manufacturer's instructions. If a laboratory modifies the manufacturer's instructions, the laboratory must establish performance specifications and validate the assay prior to performing patient testing. CLIA is not prescriptive as to how the study is performed; the Laboratory Director is responsible for defining the validation parameters.

During the public health emergency, according to the FDA, when one entity establishes equivalent performance between parallel testing of the same specimens with the new and original components (including viral transport media (VTM), and FDA's review of the validation data indicates that it could be applicable to modifications of other tests with an authorized EUA, and the laboratory agrees to FDA sharing that information for use by other laboratories, FDA posts this information on its website so other laboratories can refer to the validation for their testing, without conducting their own bridging study for the same modification. For additional information regarding FDA's policy for modifications refer to the [FDA COVID-19 Guidance](#).

In light of the current COVID-19 situation, the FDA has included information regarding viral transport media (VTM) on its [FAQs for Diagnostics Testing for SAR-CoV-2](#). Per FDA, although VTM/Universal Transport Media is the preferred transport media, alternative transport media could be used or viral transport media could be made using CDC's posted recipe. Please refer to the [FDA's FAQs](#) for further information on these issues.

In instances where the FDA has indicated that certain alternate collection devices and specimen transport media could be used, the CLIA laboratory director will need to decide if subsequent validation studies are needed before tests are performed.

Laboratory Developed Tests

The FDA published updated guidance on March 16, 2020 (found [here](#)). Under the section entitled "State Authorization of Laboratories Certified under CLIA that Meet the CLIA Regulatory Requirements to Perform High Complexity Testing," the guidance explains that states may take responsibility for tests developed and used by laboratories in their states, similar to the action the FDA granted to the New York State Department of Health. States can choose to set up a system in which they take responsibility for authorizing such tests and the laboratories will not engage with the FDA. The guidance goes on to say that the "FDA requests that the State or territory notify [FDA] if they choose to use this flexibility to expedite COVID-19 testing." If your state has not chosen to validate laboratory developed tests, please refer to the FDA for further guidance. States that cannot stand up their own oversight systems may choose to continue having laboratories submit test validations and notifications of patient testing to the FDA.

We want to clarify that laboratories performing LDTs as set forth in the FDA guidance are required to be CLIA-certified and meet the requirements to perform high complexity testing.

Contact: Questions about this document should be addressed to LabExcellence@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

David R. Wright

cc: CLIA Branch Managers
CLIA Location Staff

Frequently Asked Questions (FAQs), CLIA Guidance During the COVID-19 Emergency

1. Can the CLIA program approve an 1135 waiver for any of the CLIA Regulations during the public health emergency?

- A. The CLIA program is unable to approve section 1135 waiver requests with respect to waivers of CLIA program requirements. The section 1135 waiver authority is only applicable to specified programs (or penalties) authorized by the Social Security Act (SSA). The CLIA program does not fall into this category of programs. CMS does not have the authority to grant waivers or exceptions that are not established in statute or regulation.

However, CMS is willing to explore flexibilities, as we have, under our current authorities.

2. Are pathologists able to sign out cases remotely during the COVID-19 public health emergency?

- A. CMS will allow laboratories to utilize temporary testing sites for remote review and reporting of laboratory data/slides/images as long as specific criteria are met. See QSOG memo <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurvey/certificationgeninfopolicy-and-memos-states-and/clinical-laboratory-improvement-amendments-clia-laboratory-guidance-during-covid-19-public-health>.

3. Is proficiency testing (PT) required during the COVID-19 public health emergency?

- A. If the laboratory is performing testing and providing patient results, PT is still required and must be performed, as required by the CLIA regulations. Furthermore, the following may be of note:
- Only CMS may exercise enforcement discretion as to CLIA- requirements like PT. Unless CMS has given the directive, a PT program may not permit a laboratory to opt out of participating in a PT event while continuing to test patient specimens for reasons such as emerging public health outbreaks like seasonal influenza epidemic.
 - A PT program must immediately notify CMS, Accreditation Organizations (AO), Exempt States (ES), and laboratories if they need to postpone, suspend, or cancel an event.
 - Laboratories will not be penalized for lack of PT results if PT is postponed, suspended, or canceled with CMS's approval. However laboratories should consider performing their own self-assessment in such a scenario to ensure reliable results.
 - Laboratories should document any notification from a PT program regarding postponement, suspension or cancelation of a PT event.

- The laboratory must document on the PT result sheet that a test is not currently being performed if testing is temporarily suspended for a specific test due to staffing shortage, supply shortage, or reagent shortage.
- The inspecting agency and PT program must be notified within the timeframe of submitting PT results if a laboratory will not be submitting results due to a temporary suspension of its performing a specific test. Such notice must include the reason for that temporary suspension.

See QSOG memo, <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/clinical-laboratory-improvement-amendments-clia-laboratory-guidance-during-covid-19-public-health>

4. Can laboratories use alternate specimen collection devices (e.g., swabs) to collect specimens for COVID-19 testing?

- A. During this public health emergency, with the exceptions outlined in the memo <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/clinical-laboratory-improvement-amendments-clia-laboratory-guidance-during-covid-19-public-health>, CLIA regulations remain applicable. CLIA regulations are not prescriptive about the type of transport device, specimen collection swabs and viral transport media (VTM) that laboratories use. CMS CLIA only requires that the laboratory follow manufacturer's instructions. If a laboratory modifies the manufacturer's instructions, the laboratory must establish performance specifications and validate the assay prior to performing patient testing. CLIA is not prescriptive as to how the study is performed; the Laboratory Director is responsible for defining the validation parameters. Please refer to the [FDA COVID-19 Diagnostic Test Guidance FAQs](#) for further information.

During the public health emergency, according to the FDA, when one entity establishes equivalent performance between parallel testing of the same specimens with the new and original components (including viral transport media (VTM), and FDA's review of the validation data indicates that it could be applicable to modifications of other tests with an authorized EUA, and the laboratory agrees to FDA sharing that information for use by other laboratories, FDA posts this information on its website so other laboratories can refer to the validation for their testing, without conducting their own bridging study for the same modification. For additional information regarding FDA's policy for modifications refer to the FDA COVID-19 Guidance

In instances where FDA has indicated that certain alternate collection devices and specimen transport media could be used, the CLIA laboratory director will need to decide if subsequent validation studies are needed before tests are performed.

Additionally, CDC has posted a new [standard operating procedure](#) (SOP) for laboratories to create their own VTM in accordance with CDC's protocol.

5. Does CMS have the ability to grant my laboratory a waiver from the CLIA certification requirements so I can begin testing COVID-19 testing right away?

A. We do not have the authority to grant waivers or exceptions that are not established in statute or regulation. In the absence of such authorities, in order to do COVID-19 testing you must be a CLIA-certified laboratory that meets applicable regulatory requirements.

6. How do I apply for a CLIA certificate so my testing facility can perform COVID-19 testing?

A. While the CLIA program is a Federal program, it contracts with State Agencies to carry out certain oversight and recording functions of the CLIA program. The State Agency in the state where the laboratory is located can answer your questions and will process your application. Some states also have laboratory licensing laws separate from the CLIA regulations; laboratories in such states must meet the CLIA requirements and the state requirements.

If you would like to apply for a CLIA certificate, please submit your application form ([CMS-116, CLIA Application Form](#)) to the state ([SA Contacts](#)) where the laboratory is located.

We want to ensure that laboratories located in the United States applying for a CLIA certificate are able to begin testing for COVID-19 as quickly as possible. Once the laboratory has identified a qualified laboratory director and has provided all required information on the CMS-116 application, a CLIA number will be assigned. Once the CLIA number has been assigned, the laboratory can begin testing as long as applicable CLIA requirements have been met (e.g., establishing performance specifications).

7. What complexity testing personnel can perform the Emergency Use Authorization (EUA) COVID-19 tests?

Almost all currently EUA-authorized tests for COVID-19 are FDA-authorized for use by laboratories that meet the CLIA requirements for either moderate or high complexity testing. Therefore, testing personnel must meet the appropriate moderate or high

complexity CLIA testing personnel qualification requirements depending on which EUA-authorized tests are being used by the laboratory

8. How can I find payment information for laboratories to use when reporting COVID-19 testing?

- A. We believe most questions could be answered by [Medicare COVID-19 Testing Fact Sheet](#) and the 2 new Medicare FAQs found [here](#) and [here](#).

If you still have questions, you may send an inquiry regarding payment information at this email: CLFS_Inquiries@cms.hhs.gov.

9. Can my facility perform COVID-19 testing in their parking lots or other areas outside of the laboratory?

- A. As long as the facility has the appropriate CLIA certificates and follows applicable CLIA regulations, state regulations and guidelines, the laboratory may perform testing in the parking lot or any other designated overflow location in its facility.

10. Does CLIA have a list of laboratories performing high complexity testing?

- A. CMS CLIA only tracks laboratories as being waived or non-waived. We do not have a complete listing of laboratories that meet the requirements to perform high complexity molecular virology testing.

11. Does a laboratory have to be a Biosafety Level II laboratory in order to run a COVID-19 test?

- A. Laboratories with questions related to biosafety levels should consult CDC biosafety guidance found [here](#) or email the CDC at DLSinquires@cdc.gov.

12. Is COVID-19 categorized as Chemistry or Virology?

- A. COVID-19 testing has not been assigned a CLIA specialty or subspecialty at this time. We will inform laboratories if it is assigned a CLIA specialty or subspecialty.

Questions about this document should be addressed to LabExcellence@cms.hhs.gov