

**Frequently Asked Questions (FAQs), CLIA Guidance During the COVID-19
Emergency Updated as of 12/17/2020**

<i>FAQ #</i>	<i>Description of Change</i>
<i>14</i>	<i>Updated language</i>
<i>15</i>	<i>Updated response related to IQCP</i>
<i>26</i>	<i>Updated -EUA for home test</i>

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 [CMS QSO-20-21-CLIA](#).

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, [CMS QSO-20-21-CLIA](#)

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 [CMS QSO-20-21-CLIA](#), 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.

During the public health emergency, FDA has issued policies that may be relevant to the use of alternate specimen collection devices. Links to these policies, as well as FAQs related to them, can be found on the [FDA COVID-19 Test FAQs](#) webpage, particularly in the Testing Supply section.

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.

Please refer to the [FDA COVID-19 Test FAQs](#) for further information.

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.

Examples of facilities that would need to be CLIA certified to perform COVID-19 testing would include, but are not limited to: nursing homes, Intermediate Care Facilities for Individuals with Intellectual and Developmental Disabilities (ICF/IIDs), inpatient psychiatric facilities including Psychiatric Residential Treatment Facilities (PRTFs) and Institutions for Mental Disease (IMDs), as well as research facilities, pharmacies, urgent care centers, veterinary facilities, chiropractors and dentists.

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?

- A. 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.

Updated Response: Staff performing COVID-19 testing need to meet the CLIA personnel requirements applicable to the assay they are performing and as designated in the EUA and by the manufacturer. Nonwaived (moderate and high complexity testing) personnel requirements can be found in subpart M of the CLIA regulations (CLIA Regs – subpart M). Waived testing does not have any personnel requirements.

A link to the list of COVID-19 tests that have received EUA from the FDA is available [here](#). The site is updated as more tests receive EUAs. For ease of reference, the settings authorized in the EUAs are also noted in the EUA table on the EUA page. Tests that are noted with an "H" in the Authorized Settings are limited to use in laboratories certified under CLIA that meet requirements to perform high-complexity tests. Tests that are noted with an "H" and "M" in the Authorized Settings may be performed in laboratories certified under CLIA to perform high complexity and/or moderate complexity tests. Tests that are noted with a "W" in the Authorized Settings are deemed to be CLIA-waived for use in patient care settings operating under a CLIA Certificate of Waiver. Tests noted with an "H," "M," and "W" may be used in laboratories certified under CLIA that meet requirements to perform high complexity and/or moderate complexity tests and in patient care settings operating under a CLIA Certificate of Waiver.

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 the laboratory may perform testing in the parking lot or any other designated overflow location in its facility. *You should also contact your [State Agency](#) for further guidance regarding any state requirements.*

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

A. CMS CLIA only tracks laboratories as being waived or nonwaived. 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 assigned a CLIA specialty or subspecialty such as Chemistry, Virology, or Microbiology?

- 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.

13. What type of certificate do I need to perform COVID-19 testing?

- A. The certificate type that a laboratory would need to obtain is dependent upon the type of testing the laboratory will perform. Please refer to the CMS Admin Info memo 20-06, CMS SARS-CoV-2 Laboratory Testing Comparison ([Admin Info-20-06-CLIA](#)) for guidance.

14. Does “CLIA-waived” mean that a facility does not have to have a CLIA certificate?

- A. No. All facilities that perform testing on human specimens that provide **patient-specific** results for the diagnosis, prevention, treatment of any disease, or the assessment of health of human beings are required to have a CLIA certificate to perform testing, except that **CMS is temporarily exercising enforcement discretion under CLIA** for **certain types of surveillance testing** as described in [the CLIA Surveillance Testing FAQs](#) and [CLIA and University Lab Testing FAQs](#). “CLIA-waived testing” may be performed in facilities operating under a CLIA Certificate of Waiver (CoW), Certificate for Provider Performed Microscopy (PPM), Certificate of Compliance (CoC), Certificate of Accreditation (CoA), and whether a particular test is deemed “CLIA-waived” is a determination made by the FDA. Please refer to FAQs #16 and #17 for more information.

15. Can a laboratory develop an Individualized Quality Control Plan (IQCP) for COVID-19 test systems?

- A. The manufacturer’s quality control (QC) instructions for all tests that have Emergency Use Authorization (EUA) must be followed, to include quality control (QC). Because QC for EUAs must be followed, and no deviations to the QC requirements in the EUA are permitted, IQCP is not applicable to EUAs.

Please note: The laboratory director may determine, based on risk assessment that additional QC needs to be implemented above what is required in the EUA Instructions for Use (IFU).

Updated response: *During the COVID-19 public health emergency CMS has determined that IQCP is an option for EUA tests classified as non-waived (authorized for use in moderate or high complexity settings) when manufacturers’ QC is less stringent than the CLIA quality control requirements at 42 CFR § 493.1256. The laboratory director may determine, based on risk assessment, that additional QC is necessary above what is otherwise required in the EUA Instructions for Use (IFU).*

The manufacturer’s QC instructions for all tests that have an EUA need to be followed. However, if the Instructions for Use (IFU) indicate laboratories should perform external “QC in accordance with applicable local, state, and/or federal regulations”, then for purposes of CLIA, the laboratory needs to follow the non-waived CLIA quality control

*requirements found at 42 CFR 493.1256 or develop an IQCP, as well as any other QC instructions provided by the manufacturer. If the laboratory opts to implement an IQCP, refer to the State Operations Manual, Appendix C ([Interpretive Guidelines](#)) page 198. The Quality Control Plan must include the **number, type, frequency of testing, and criteria for acceptable result(s) of the quality control(s)**, and must be approved by the laboratory director.*

Laboratories should contact the applicable [State Agency](#) for further guidance regarding state requirements. Accredited laboratories should contact the applicable Accreditation Organization (AO) directly to determine the AO standards related to IQCP.

16. If the FDA authorizes a COVID-19 test under an EUA for use at “patient care settings outside of the clinical laboratory environment,” “near patient testing,” and “point of care” does this mean that the test is CLIA waived?

- A. In cases where these terms are used in EUAs, and the FDA has indicated the testing may be performed in a waived setting and the FDA has deemed such test to be appropriate for use in a CLIA waived setting, it may be used in a location with a Certificate of Waiver for the time period of the emergency. Because FDA does not perform a complexity categorization to tests under Emergency Use Authorization, CMS refers to the intended use stated in the IFU. The settings in which an EUA authorized test may be used are described in the Letter of Authorization (Under the Federal Food, Drug & Cosmetic Act, the FDA may determine that a test shall be deemed to be in a particular category). The terms “patient care settings outside of the clinical laboratory environment,” “near patient testing,” and “point of care” generally refer to settings that are equipped with the instrumentation and appropriately trained personnel necessary to perform the test per the EUA’s conditions of authorization, and may include settings such as hospitals, physician offices, urgent care, outreach clinics, pharmacies, and temporary patient care settings that have appropriately trained personnel to perform the test and are operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. Please note that this would also apply to Certificate of PPM laboratories.

An up-to-date list of the tests that have received an EUA from FDA, including authorized settings, may be found at the following link: [FDA EUA COVID-19 Test List](#). Tests appropriate for use in a CLIA waived setting will be noted with a W in the Authorized Settings column on FDA’s EUA webpage.

17. Can a laboratory perform antibody testing with a Certificate of Waiver?

- A. Only tests authorized by FDA for use under a Certificate of Waiver may be used in such an environment. An up-to-date list of the tests that have received an EUA from FDA, including authorized settings, may be found at the following link: [FDA EUA COVID-19 Test List](#). The site is updated as more tests receive EUA.

The “Authorized Setting(s)” column describes the setting in which a test is authorized to be performed, i.e., a waived, moderate complexity or high complexity setting. You may also refer to [ADMIN 20-06-CLIA](#) for testing requirements for COVID-19.

Any COVID-19 tests without an EUA from the FDA shall be treated as a high complexity test regardless of whether the manufacturer intends for the test to be point-of-care/waived. In order to perform COVID-19 testing using a test that has not been issued an EUA from the FDA, you must be a CLIA certified laboratory that meets regulatory requirements to perform high complexity testing under 42 C. F. R. §§ 493.1441 through 493.1495 of the CLIA regulations. The CLIA regulations can be accessed at: [CLIA Regulations](#). Please also refer to FDA's [COVID-19 Test Guidance](#), which explains FDA's policies regarding CLIA certified laboratories that meet regulatory requirements to perform high complexity testing under §§ 493.1441 through 493.1495 of the CLIA regulations, that are performing COVID-19 testing using a validated test that has not yet been issued an EUA from the FDA.

18. What does it mean if a test is not on the [FDA EUA COVID-19 Test List](#)?

- A. Tests not on the FDA EUA COVID-10 Test List have not received an EUA from FDA. Any COVID-19 test without an Emergency Use Authorization (EUA) from the FDA shall be treated as a high complexity test under the CLIA regulatory scheme. In order to use a test for COVID-19 that does not have a FDA EUA, the laboratory must be a CLIA certified laboratory that meets regulatory requirements to perform high complexity testing under §§493.1441 through 493.1495 of the CLIA regulations. You may access the CLIA regulations at: [CLIA Regulations](#). Please also refer to [FDA's COVID-19 Test Guidance](#), which explains FDA's policies regarding CLIA certified laboratories that meet regulatory requirements to perform high complexity testing under §§493.1441 through 493.1495 of the CLIA regulations, that are performing COVID-19 testing using a validated test that has not yet been issued an EUA from the FDA.

Please see the list of FDA authorized tests to determine if the COVID-19 test you would like to perform in your facility is an FDA authorized test. This FDA website includes the setting in which each test is authorized for use, i.e., a waived, moderate complexity or high complexity setting.

19. What should a laboratory do if its CLIA certificate has expired or is about to expire?

- A. CMS is currently working to evaluate certificate expiration dates and extend certificates for laboratories whose certificates have expired or near expiration. Please work with your [State Agency](#) to address issues about your certificate.

20. Are the testing personnel requirements for the COVID-19 testing being waived during this public health emergency?

- A. No. Staff who perform COVID-19 testing need to meet the CLIA personnel requirements applicable to the assay they are performing and as designated in the EUA and by the manufacturer. Nonwaived (moderate and high complexity testing) personnel requirements can be found in subpart M of the CLIA regulations ([CLIA Regs – subpart M](#)). Waived testing does not have any personnel requirements.

21. Who can order a test for COVID-19?

- A. The CLIA regulations at §493.1241 state that the laboratory must have a written or electronic request for patient testing from an authorized person. You will need to contact your State Agency for further guidance regarding any state requirements.

22. Our laboratory has a multi-site CLIA certificate that limits the laboratory to 15 moderate and waived tests. Are any exceptions being made to allow more than the maximum of 15 tests during this public health emergency?

- A. No. Laboratories that wish to qualify under the not-for-profit or Federal, State, or local government laboratories that perform limited public health testing exception need to ensure that the combination of moderately complex and waived tests does not exceed 15 tests per CLIA certificate. If the laboratory decides to add a specific test that would increase the combination of tests being performed to greater than 15 tests, the laboratory will need to designate which of the 15 tests they wish to continue to perform under this multisite exception or change its certification.

23. What should a laboratory do if it has decided to temporarily close during this COVID-19 emergency?

- A. In the event that a laboratory chooses to temporarily close during the COVID-19 public health emergency, the laboratory must:
- 1) Document the timeframe and reason for the temporary closure;
 - 2) Notify the inspecting agency and Accreditation Organization (if applicable) about the temporary closure;
 - 3) Notify the PT Program; and
 - 4) Maintain documentation of this notification.

24. Is a laboratory required to submit an application and test menu update for a laboratory with a current Certificate of Waiver if the laboratory wants to add a waived test during the COVID-19 public health emergency?

- A. No. Laboratories with a current Certificate of Waiver (CoW) are not required to submit a new application or notify CMS when adding an additional waived test. You should also contact your State Agency for further guidance regarding any state requirements.

25. What does a laboratory need to do if the specimen type being used for test is not listed in the EUA authorization?

- A. The manufacturer's instructions for all tests that have been issued an EUA must be followed, to include the authorized specimen type.

26. Has the FDA authorized any EUA tests for COVID-19 for at-home testing?

- A. At this time, several manufacturers have received an EUA for at home collection of specimens to be sent to a laboratory for processing and test reporting. FDA has not yet issued an EUA for any test to be completely used and processed at home.

Updated Response: *On 11/17/2020, the FDA authorized the first prescription home use COVID test, Lucira COVID-19 All-In-One Test Kit under emergency use authorization. In addition to home use, this test is authorized for use at the Point of Care (POC), in patient care settings operating under a CLIA Certificate.*

For more information, please see the Helpful Link, “FDA EUA COVID-19 Test List” below.

27. Can a laboratory use expired viral RNA mini kits or swabs if they pass the QC in the laboratory? Would this use of these expired reagents or swabs be acceptable as long as the internal controls/external controls are valid with the test?

- A. During the COVID-19 public health emergency, in order to address the concern over COVID-19 reagent and swab supply problems, CMS will allow laboratories to use expired COVID-19 test kits, reagents, and swabs. If doing so deviates from the test manufacturer’s authorized instructions for use, the use would not be authorized under the EUA and should not be represented as such. As stated in the CLIA Interpretive Guidelines located [here](#), “When in-date reagents are unavailable, it may become necessary to frame written policies for their temporary use beyond their expiration dates until non-expired supplies become available. Under no circumstances, however, should a laboratory adopt policies that would allow for the regular use of expired reagents.” Thus, laboratories may use expired supplies until non-expired supplies become available provided that they put policies and procedures in place to ensure the reagents are performing as expected (e.g., ensuring that any expired supplies pass quality control tests with each assay run).

28. What do I need to do if my facility wants to assist with the administration’s Opening Up America Again initiative and only perform testing during this emergency?

- A. CMS wants 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 CLIA regulations 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). We encourage any laboratory that would

like to perform COVID-19 testing to reach out to their State Agency ([State Agency Contacts](#)) and submit a CLIA application ([CMS-116 Application Form](#)).

As long as the temporary site provides testing consistent with the laboratory's CLIA CoW, PPM, CoC, CoA, under the direction of the primary site's laboratory director, the laboratory should be able to temporarily perform testing in an alternate location. If a laboratory finds the need to become a permanent site, they must apply for another CLIA certificate.

Please note: If a laboratory decides to perform COVID-19 testing during the public health emergency, the laboratory must make provisions to ensure that all records are retained and available for at least two years after the cessation of testing.

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

Helpful Links:

- QSO Memo, Performance Specification Verification of Assays Authorized Under Emergency Use (EUA, [CMS QSO-18-19-CLIA](#))
- QSO Memo, Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency, [CMS QSO-20-21-CLIA](#)
- QSO Administrative Memo, CMS SARS-CoV-2 Laboratory Testing Comparison and CMS COVID-19 Testing Infographic, [Admin Info-20-06-CLIA](#)
- [CLIA Surveillance Testing FAQs](#)
- [CLIA POC Antigen Test FAQ](#)
- [CLIA University Lab Testing FAQs](#)
- CLIA Regulations 42 C.F.R § 493, [CLIA Regulations](#)
- FDA Emergency Use Authorization (EUA) Test List, [FDA EUA COVID-19 Test List](#)
- FDA Frequently Asked Questions (FAQs), [FDA COVID-19 Test FAQs](#)
- FDA COVID-19 Policy for Coronavirus Testing, [FDA COVID-19 Test Guidance](#)
- [CDC COVID-19 Information for Laboratories](#)

Helpful emails:

- FDA, General COVID-19 questions: COVID19DX@fda.hhs.gov
- FDA, Reporting fraudulent products: FDA-COVID-19-Fraudulent-Products@fda.hhs.gov
- CMS Payment Questions: CLFS_Inquiries@cms.hhs.gov
- CDC, General COVID-19 questions: DLInquiries@cdc.gov