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

Ref: QSO-22-13-CLIA EXPIRED

DATE: December 4, 2025

TO: State Survey Agency Directors

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

SUBJECT: ***EXPIRED:*** Clinical Laboratory Improvement Amendments (CLIA) Guidance for Temporary Testing Sites under the Multiple Site Exception

Memo Information:
Memo expiration date: 2025-12-04
Original release date: 2022-02-28

Memorandum Summary

CMS is issuing this memorandum to clarify CLIA guidance during the COVID-19 public health emergency related to the temporary testing site multiple site exception and the enforcement discretion related to remote testing.

- The CLIA regulations allow for laboratories to operate with a multiple site exception to its certificate as outlined in the CLIA regulations at §§493.35(b)(1), 493.43(b)(1) and 493.55(b)(1).
- Operating under a multiple site exception allows laboratories the flexibility to expand access to SARS-CoV-2 testing by way of temporary testing sites during the COVID-19 public health emergency.
- The CLIA regulations do not define a temporary testing site or limit the number of temporary sites under a single CLIA certificate.
- CMS is clarifying notification requirements for temporary testing sites.
- CMS is clarifying the enforcement discretion related to remote review of clinical laboratory data, results and pathology slides outlined in QSO-20-21-CLIA.

Background:

CMS continues 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. We are clarifying CLIA guidance related to the temporary testing site multiple site exception and the enforcement discretion allowed during the COVID-19 public health emergency related to remote testing. Laboratories that are accredited

must follow Accreditation Organization (AO) standards. All laboratories also need to follow any State laws governing laboratories, which may be more stringent than CLIA.

Due to the public health emergency posed by COVID-19 and the urgent need to expand laboratory capacity, CMS is clarifying requirements for laboratories operating with a multiple site exception under its CLIA certificate. While we do not want to limit access to testing, we need to ensure the identity of the primary laboratory and all temporary testing sites can be accounted for at any given time. 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:

Temporary Testing Sites Multiple Site Exception

CMS issues this memorandum to provide guidance for CLIA surveyors and laboratories regarding the notification requirements for laboratories operating temporary testing sites. For each certificate type under the CLIA regulations (42 CFR sections 493.35(b), 493.43(b), and 493.55(b)), some exceptions allow a laboratory, in specific circumstances, to apply for a single certificate for multiple testing sites. Specifically, the regulations allow laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations, to be covered under the certificate of the designated primary site or home base, using its address. At the beginning of the COVID-19 public health emergency, many laboratories expanded testing to additional temporary sites to keep up with the testing demand. For purposes of this memorandum, 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. These sites include but are not limited to parking lots, schools, and pop-up sites. All work performed at the temporary testing sites falls within the primary site's certificate parameters.

This memo outlines the notification requirement regarding multiple site testing locations. A laboratory seeking a multiple site exception is required to mark the applicable exception on its completed Form CMS-116 (CLIA application) and submit (or resubmit, as appropriate) the form to CMS. A laboratory may provide a separate list of its temporary testing sites and attach it to the CMS-116. In addition, the laboratory must provide the name, address, and telephone number of each site that will operate under the exception. In addition, CMS' policy since November 2008, outlined in Admin Info-09-09, requires laboratories under these exceptions to submit written notification of any change in multiple site status. CMS will require this information from any laboratory applying for a multiple site exception. Written notification of any change in multiple site status may be submitted by email, fax, or hard copy letter.

Surveyors may request, at any time, that a laboratory provide a list of its temporary testing sites and may also request that the temporary testing site provide the primary laboratory's CLIA number under which it is operating. Surveyors will not be expected to track down laboratories that have previously applied with a multiple site exception to collect this information. However,

if surveyors become aware of existing laboratories that have temporary testing sites, they can request the information above at that time. Collecting this information will better allow CMS to locate the primary laboratory for an identified temporary testing site when addressing complaints from the public.

In addition, it is recommended that temporary testing sites post a copy of the CLIA certificate of the laboratory under which they are operating.

Notification of Temporary Testing Locations for Multiple Site Exception

	Notification Requirement
Initial Form CMS-116 with multiple site exceptions	• Section V. Multiple Sites must be completed; and • A list of temporary testing sites must be included on or attached to the Form CMS-116.
Current CLIA Number **with no multiple site** exceptions in ASPEN 116 Web → adding multiple site exceptions	• A new Form CMS-116 must be submitted to the State Agency (SA) with Section V. Multiple Sites completed; and • A list of temporary testing sites must be included on or attached to the Form CMS-116.
Current CLIA Number **with multiple site** exceptions in ASPEN 116 Web → adding additional multiple site exceptions	• Written notification must be submitted to the SA when changes occur to the number or location of temporary testing sites.

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 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. 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 parameters of the primary site's certificate. A pathologist's home may be the remote testing site.

Laboratories that choose to utilize testing sites 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.
- As per §493.1251, the primary site must have a written procedure manual for all tests, assays, and examinations performed by the laboratory. It 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.
- Equipment, supplies, reagents, and other similar items needed at the remote site are not permanently kept at a remote testing site.
- The remote site complies with other applicable Federal laws, including HIPAA.

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.

CMS wants the public to have confidence in the quality of testing services being performed by any given laboratory, whatever the location (e.g., hospital, doctor's office, or a temporary testing site). CMS has an established process to allow anyone to file a formal complaint against a laboratory at any time. The complaint process can be found on the CLIA website here.

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
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:
Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.

Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

Get guidance memos issued by the Quality, Safety and Oversight Group by going to CMS.gov page and entering your email to sign up. Check the box next to "CCSQ Policy, Administrative, and Safety Special Alert memorandums" to be notified when we release a memo.

TEMPORARY COVID-19 TESTING SITES: ASSURING LABORATORY QUALITY & SAFETY

BE MINDFUL WHEN VISITING COVID-19 TESTING SITES. Fraudsters are attempting to obtain your personal and medical information, including your Medicare number. The personal information collected can be used to fraudulently bill federal health care programs and commit medical identity theft. Visit hhs.gov/coronavirus/testing/index.html for a list of available testing sites.

WHEN VISITING A TESTING SITE, be observant and make sure testing personnel are wearing appropriate protective equipment (i.e., gloves, masks).

IF THIS IS A RAPID TEST, results of the test must be evaluated within the timeframe stated in the manufacturer's instructions. You can ask the testing personnel how long it will take to read the test results.

PATIENT TEST RESULTS NEED TO BE DOCUMENTED AND REPORTED. Ask the testing personnel how your results will be documented and reported.

CONSUMERS CAN FILE COMPLAINTS if they are concerned about the quality of testing. Information is available here: CLIA Complaint Brochure. Any laboratory complaints can be directed to the appropriate State Agency.

BENEFICIARIES SHOULD BE CAUTIOUS of unsolicited requests for their personal, medical, and financial information. Medicare will not call beneficiaries to offer COVID-19 testing, related products, services, or benefit review. If you receive a suspicious call, hang up immediately.

DO NOT RESPOND TO OR OPEN LINKS in text messages about COVID-19 testing sites from unknown individuals.

BE AWARE OF INDIVIDUALS PRETENDING TO BE COVID-19 CONTACT TRACERS. Legitimate contact tracers will never ask for your Medicare or financial information, or offer to schedule your COVID-19 test.

IF YOU SUSPECT COVID-19 HEALTH CARE FRAUD, report it immediately to 1-800-MEDICARE (1-800-633-4227)

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