

Executive Office of Health and Human Services

Department of Public Health
Bureau of Health Care Safety and Quality

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**Memorandum**

**TO:** Clinical Laboratory Directors

**FROM:** Elizabeth D. Kelley, MPH, MBA, Director

Bureau of Health Care Safety and Quality

**SUBJECT:** Clinical Laboratory Program Updates:

* Temporary Laboratory License for CLIA-waived COVID-19 Testing Purposes; and
* Clinical Laboratory Alternate Sites

**DATE:** June 14, 2021

The Massachusetts Department of Public Health (DPH) continues to work with state, federal and local partners on the outbreak of Coronavirus Disease 2019 (COVID-19), caused by the virus SARS-CoV-2, and we continue to appreciate the essential role you have in responding to this evolving situation.

Pursuant to the Commissioner Public Health Order dated June 14, 2021, facilities wishing to conduct only CLIA-waived COVID-19 testing and no other clinical laboratory testing may apply to DPH’s Clinical Laboratory Program for a temporary COVID-19 laboratory license. **Facilities and clinical laboratories already exempt from clinical laboratory licensure under Massachusetts General Laws and Department regulations need not apply for the temporary COVID-19 license.**

Applications for a temporary COVID-19 laboratory license for may be found as “Attachment A” to this document as well as on DPH’s COVID-19 Guidance and Directives Website.

Applicants for a temporary COVID-19 laboratory license must:

* Complete the attached form and provide a copy of a CLIA certificate, CLIA number, or CMS-116 CLIA application to the Clinical Laboratory Program; and
* Include in the submission all testing sites with addresses that will be an extension of the temporary license.

A facility applying for a temporary COVID-19 laboratory license will not be approved unless the applicant has an assigned CLIA number.

Facilities granted a temporary COVID-19 laboratory license must:

* Adhere to all CLIA, federal and state laws, regulations and requirements, including, but not limited to, storage and handling of equipment and testing samples and supplies; and
* Maintain proper infection control and use recommended personal protective equipment, including an N95 or higher-level respirator (full face shield and face mask if N-95 not available), eye protection, gloves, and a gown.

A temporary COVID-19 laboratory must name a laboratory director, who shall be responsible for clinical oversight of the temporary COVID-19 laboratory. The Department waives 105 CMR 180.050 through 180.070, in part, to allow a licensed physician, a nurse practitioner, a physician assistant, licensed pursuant to M.G.L. c. 112, or an individual who otherwise qualifies under M.G.L. c. 111D, Section 7.

A temporary COVID-19 laboratory must employ appropriately trained healthcare personnel. The Department waives 105 CMR 180.100 through 180.200, in part, to allow appropriately trained healthcare personnel to be employed by the temporary COVID-19 laboratory with supervision from the laboratory director. Only healthcare personnel with appropriate training and competency are authorized to perform specimen collection for purposes of COVID-19 testing. All personnel performing blood collection, nasopharyngeal (NP) or anterior nares (AN) specimen collection must be trained and demonstrate competency to be able to safely collect specimens. All unlicensed healthcare personnel must be appropriately supervised.

Unless otherwise stated in the Public Health Order, temporary COVID-19 laboratories are subject to all other statutory and regulatory requirements applicable to clinical laboratory licensure and operation, including M.G.L. c. 111D and 105 CMR 180.000. The failure to adhere to statutory and regulatory requirements may be grounds for the denial, revocation or refusal to renew a license.

***Extension Sites for CLIA-Waived COVID testing***

In addition to the temporary COVID-19 license, the Department will approve temporary extension sites for CLIA-Waived COVID-19 testing sites. Applicants for both temporary licenses and laboratories with an existing license may request extension sites.

The extension site must meet all standards for clinical laboratories and be an extension site for an existing laboratory with an existing clinical laboratory license. The laboratory director for the existing clinical lab will be responsible for the extension site.

The extension site must adhere to the following requirements:

* Must be covered under a current CLIA certificate that is appropriate for the testing performed.
* Maintain all federal and state standards for storage of equipment and testing samples and supplies, and environmental cleaning, sanitization and appropriate decontamination, medical recordkeeping and patient confidentiality;
* Provide only COVID-19 testing;
* Adhere to all policies and procedures of the clinical lab under which the license is operating including COVID-19 testing procedures and HIPAA privacy laws.
* Include immediate access to hand wash sinks or other forms of hand hygiene.

Additional information pertaining to the CLIA enforcement discretion of remote sites may be found here:

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

Please visit DPH’s website that provides up-to-date information on COVID-19: <https://www.mass.gov/2019coronavirus>