


ALERT

MEMORANDUM

TO: Communicable and Reportable Disease Testing Laboratories

FROM: Ranada Cooper 
Associate Director
Office of Health Facilities

DATE: September 29, 2023

SUBJECT: **Communicable and Reportable Disease License Halted**

This is a notice from DC Health, Health Regulation and Licensing Administration (HRLA), regarding HRLA's termination of the issuance of licenses to operate a Communicable and Reportable Disease Testing Laboratory. HRLA will no longer accept or process applications for this type of license or renew existing licenses.

On or about June 15, 2023, HRLA determined to discontinue the issuance of the Communicable and Reportable Disease Testing Laboratory license. The primary reason for this determination is the current lack of regulations to specify and clarify the standards and requirements imposed by the Clinical Laboratory Act of 1988 ("the Act"), effective March 16, 1989, D.C. Law 7-182; D.C. Official Code § 44-201 *et seq.*, as amended.

Although the Act authorizes DC Health to issue clinical laboratory licenses, regulations have not yet been adopted to properly implement the requirements of the Act. For this reason, the issuance of licenses for the operation of Communicable and Reportable Disease Testing Laboratories has been halted.

Importantly, this decision by HRLA should not impact the ability of such laboratories to operate in the District. Pursuant to D.C. Official Code § 44-202(c), "clinical laboratories that, prior to March 16, 1989, were not or would not have been subject to licensure in the District of Columbia may operate without a license until one year after the issuance of rules pursuant to D.C. Official Code § 44-213." Because regulations have not yet been issued, this provision remains effective. Thus, clinical laboratories that would otherwise be required to obtain licensure are currently permitted to continue operating without licenses.

Soon, DC Health will issue regulations to govern the licensure and operations of clinical laboratories in the District. These regulations will provide much needed guidance and clarity to both HRLA staff and the provider community. In the meantime, please be advised that HRLA will continue to require certification pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (See 42 USC § 263 and 42 C.F.R. § 493).

If you have any questions or need further information, please contact the Health Care Facilities Division via email at dchealth.clia@dc.gov or hcf.d.hrla@dc.gov.