

Janet T. Mills
Governor

Sara Gagné-Holmes
Commissioner



Maine Department of Health and Human Services
Maine Center for Disease Control and Prevention
Health and Environmental Testing Laboratory
#12 State House Station
47 Independence Drive
Augusta, Maine 04333-0012
Tel; (207) 287-1717; Fax (207) 287-6832
TTY: Dial 711 (Maine Relay)

On January 1st, 2025, the CLIA Clinical Microbiology section of the Health and Environmental Testing Laboratory at 47 Independence Drive, Augusta, Maine, 04333 will be updating our testing menu. This is in response to the Department of Health and Human Services Food and Drug Administration 21 CFR Part 809 [Docket No. FDA-2023-N-2177] update:

“This final rule amends FDA’s regulations in part 809 (21 CFR part 809) to make explicit that “in vitro diagnostic products” (IVDs) are devices as defined in section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(h)(1)) including when the manufacturer of the IVD is a laboratory. In conjunction with this amendment, FDA is phasing out its general enforcement discretion approach for laboratory developed tests (LDTs) so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs, as discussed further in section V of the preamble to the rule.” -<https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/laboratory-developed-tests-regulatory-impact-analysis-final-rule>.

Laboratories are still required to submit all required samples to Health and Environmental Testing Laboratory per 10-144: DEPARTMENT OF HEALTH AND HUMAN SERVICES MAINE CENTER FOR DISEASE CONTROL AND PREVENTION Chapter 258: CONTROL OF NOTIFIABLE DISEASES AND CONDITIONS RULE APPENDIX A NOTIFIABLE DISEASES AND CONDITIONS LIST.

- The following whole genome sequencing assays will be converted from diagnostic assays to surveillance assays: *Campylobacter* speciation, *Salmonella* genotyping, *E. coli* genotyping, *Vibrio cholerae* toxin testing, *Salmonella* tartrate positivity, *Neisseria meningitidis* genotyping, *Haemophilus influenzae* genotyping, bacterial virulence factors gene analysis, bacterial resistance gene analysis, Mycobacterium other than Tuberculosis (MOTT) speciation, clinical viral metagenomics.
- The following real-time PCR assays will no longer be offered: *Cryptosporidium* speciation and *Bordetella* speciation.
- The following PCR assay will no longer be offered: Plasmodium
- The following serotyping assay will no longer be offered: *Neisseria meningitidis*

DocuSigned by:
11/4/2024
762734DCD4774AD...

Dr. Daniel Jones
CLIA Laboratory Director
CLIA ID # 20D649525