



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Care Safety and Quality
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Circular Letter: DHCQ 15-11-645

TO: Clinical Laboratories

FROM: Eric Sheehan, JD
Interim Bureau of Health Care Safety and Quality

SUBJECT: Addition of CLIA-Waived Blood Lead Testing to Exempt Test List

DATE: November 4, 2015

The purpose of this circular letter is to notify physician office laboratories (POLs) that CLIA-Waived Blood Lead Testing has been added to the Clinical Laboratory Program's Exempt Test List.

In Massachusetts, clinical laboratories operated by three or more licensed physicians are exempt from state licensing requirements, provided that they operate the laboratory exclusively in connection with the diagnosis and treatment of their own patients and they perform only those tests that are listed on the "Exempt Test List".

Note that POLs operated by not more than two licensed physicians are exempt from state licensing requirements, regardless of the type of tests performed.

The updated Exempt Test List may be found in Attachment A.

If you have any questions about this guidance, please contact Pamela Waksmonski, Clinical Laboratory Program Manager at (617) 753-7307 or Pamela.Waksmonski@state.ma.us.

ATTACHMENT A
EXEMPT TEST LIST

“Exempt” tests are tests performed in a physician office laboratory which are generally non-instrumental in nature and the results of which are determined by observation of a visual signal. Clinical laboratories operated by three or more licensed physicians for the diagnosis and treatment of their own patients are exempt from state licensure if they perform only tests listed on the Department’s Exempt Test List. If the laboratory performs any testing not on the Exempt Test List, then all tests performed by the laboratory must comply with 105 CMR 180.000, *The Operation, Approval and Licensing of Clinical Laboratories*.

The following tests are classified as “Exempt”:

- Cholesterol, Capillary Whole Blood
- Erythrocyte sedimentation rate
- Glucose, Capillary Whole Blood
- Hematocrit, Capillary Whole Blood
- Hemoglobin, Capillary Whole Blood
- Latex Slide Tests, qualitative (no dilution of sample or reagent required)
- Lead, Blood, Blood, CLIA-Waived
- Occult Blood (stool) tests
- Ovulation Test (LH) by visual comparison, CLIA-waived
- Pregnancy Test – Qualitative (Urine and Serum)
- Prothrombin Time, Capillary Whole Blood
- Scotch Tape Prep for Pin Worm Ova
- Serological tests directly from swab
- Sickle Cell Screening
- Throat Culture, screening only (including Bacitracin Disk)
- Urinalysis – Dipstick with microscopy
- Urine Culture, screening only (growth or no growth)
- Wet Smears (e.g., trichomonas, yeast, KOH)

Notes: Clinical laboratory testing requires an appropriate CLIA certificate.
Participation in a Proficiency Testing (PT) program is strongly recommended.
It is recommended that all confirmatory blood lead tests are performed on venous blood samples.

Updated: 11/04/2015