

Maryland Department of Health, Laboratory Advisory Committee

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Overview

- The Maryland Department of Health, Laboratory Advisory Committee (LAC), was established by the Maryland State Legislature in 1989 and is codified in Health General Code Ann. § 17-217.
- The LAC was created to advise and make recommendations to the Secretary of the Maryland Department of Health on whether certain clinical laboratory tests should be granted excepted status.
- Excepted status refers to a clinical laboratory test that is authorized by the Secretary to be performed without a permit (i.e. Letter of Exception signed by the Secretary).

- Typically, these tests are non-instrumental or rapid diagnostic tests (that use a dipstick or cassette instead of laboratory equipment) and are quick and/or easy to perform.
- Health care providers (particularly physician offices) and Health Awareness Testing sites (health fairs/shopping malls) apply for and obtain Letters of Exception to conduct screening for certain medical conditions (e.g., cholesterol, whole blood glucose, etc.).
- Consequently, the LAC was formed to better protect healthcare consumers who could be adversely affected by the results of waived tests that were incorrectly performed in unlicensed labs that are not subject to inspection; while at the same time allowing tests (that would benefit patient care) to be properly performed by healthcare providers (e.g. physician offices, health fairs etc.).

Tests Approved for Excepted Status

As per COMAR 10.10.03.02, a Physician Office Laboratory or Point-of-Care-Laboratory operating under a Letter of Exception, may perform the following laboratory tests that have been approved for excepted status:

- Whole blood glucose;
- Dermatophyte screen;
- Dipstick glucose;
- Dipstick urinalysis;
- Gram stain;
- Group A streptococcal screen;
- Hematocrit;
- Hemoglobin;
- Infectious mononeucleosis slide or card test;
- Microscopic urinalysis;
- Occult blood;
- Pinworms;
- Potassium hydroxide skin preparations;
- Rheumatoid factor slide agglutination test
- Sickle-cell screen;
- H. pylori test with a single use test device for nonforensic testing;
- Fructosamine test with a single use test device;

- Heterophile antibodies test with a single use device;
- Urine bacteria colony count;
- Wet mounts;
- Influenza antigen test;
- Hemoglobin A1c test using a whole blood specimen;
- Qualitative test for bladder cancer markers;
- Brain natriuretic peptide (BNP) test using a whole blood specimen;
- Fern test for qualitative detection of:
 - Amniotic fluid crystallization
 - Estrogenic activity;
- Qualitative semen analysis, limited to detecting:
 - The presence or absence of sperm; or
 - Sperm mobility;
 - Nitrazine vaginal pH test;

- Qualitative immunochromatographic test;
- Microalbumin-creatinine urinalysis test;
- Screening tests for urine or saliva performed on FDA cleared for home use or FDA approved single use test devices;
- Qualitative enzyme activity test using a chromogenic substrate of bacterial sialidase for use in the detection of bacterial vaginosis;
- Qualitative immunochromatographic test to detect the presence of *Trichomonas vaginalis* antigens;
- CLIA waived Prothrombin Time/International Normalized Ratio (PT/INR);
- CLIA waived blood lipid analysis for cholesterol, HDL, LDL and triglycerides
- Whole blood lead testing on a CLIA waived analyzer;
- CLIA waived urine drug screens.

Composition of the Laboratory Advisory Committee

- **The Laboratory Advisory Committee consists of one (1) representative from each of the following organizations:**
 - **Academy of Family Practitioners**
 - **American Academy of Pediatricians**
 - **American College of Physicians**
 - **American Society for Clinical Pathology**
 - **American College of Pathology**
 - **Advanced Medical Technology Association**

- **The Secretary may also appoint any other individuals or representatives at his or her discretion, the LAC also has:**
 - **One (1) public representative;**
 - **One (1) representative from the University of Maryland, School of Pharmacy; and**
 - **One (1) representative from the Maryland Department of Health, Office of Health Care Quality (Laboratory Licensing).**
 - **Each representative is appointed for a term of two years; and the Chair of the LAC is designated by the Secretary.**

Expectations of Committee Appointees

- Appointees should stay abreast of new scientific principles, techniques and developments regarding laboratory testing that may be of interest to the LAC, including laboratory tests that may qualify for excepted status in the State of Maryland.
- Appointees should also periodically follow-up with their respective organizations regarding potential issues and/or concerns in the medical laboratory community that may be suitable for discussion by LAC.

Role of the Laboratories Administration

- **The Laboratories Administration provides administrative support and assistance for the Laboratory Advisory Committee.**
- **The State Lab also reviews proposed legislation during each legislative session to determine if any proposed bills will have an impact on clinical laboratory testing and particularly, clinical laboratory tests that will require excepted test status to be performed in the State of Maryland (i.e. House Bill 681 – Medical Laboratories – Advertising or Solicitation of Business – Repeal of Prohibition (2018) and 23andMe).**

Frequency of Laboratory Advisory Committee Meetings

- Although there are no statutory requirements for the total number of meetings that must be held annually, face-to-face LAC meetings are held at least once per year.
- However, upon receiving proposed legislation or written requests for the Secretary to authorize excepted status for a clinical laboratory test, emergency meetings can be held on an as needed basis.

Communication Between Laboratory Advisory Committee Appointees

- In an effort to enable the Laboratory Advisory Committee to communicate more effectively, the Office of Information Management Services will be requested to create a LAC email group.
- The email group will allow confidential communication/interaction by appointees to discuss matters pertinent to the LAC.

Thank you!

We are honored to have you on
the Laboratory Advisory
Committee and your service is
greatly appreciated!