



Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

Performing CLIA Waived Tests in Maryland

To conduct CMS CLIA waived tests in Maryland, a laboratory must have a CLIA Permit and either a Maryland Laboratory Permit or a Letter of Exception. All laboratories must follow the same CMS CLIA Waived requirements, including the requirement to follow the manufacturer instructions for performing the test. All applicants must pay the federal CMS CLIA \$180 every two years for CLIA certification regardless of the state status of the test.

The same application form is used for a Maryland Laboratory Permit or a Letter of Exception. There is no cost for the application. To add a new CLIA waived test, the laboratory must complete a Change Form https://health.maryland.gov/ohcq/Labs/docs/LabsApps/Change_Form_e.pdf and submit it to MDH Office of Health Care Quality(OHCQ). Generally, OHCQ processes the request in 1 - 2 days.

If a CLIA waived test is not on the Excepted Test list (Schedule B, State Compliance Application), the applicant selects the test discipline under Schedule A of the State Compliance Application. If certain medical professionals in Maryland want to run an FDA approved CLIA waived test without a laboratory license the test must be on the Excepted test list under COMAR 10.10.03.02. The procedures to add new tests to the Excepted test list by review of the Laboratory Advisory Committee are outlined under COMAR 10.10.02.01(E). Generally, the complete process to add an approved Excepted test by regulation from beginning to end takes about 9 months to one calendar year.

If you have any questions or would like to discuss the process further, please contact the [Office of Health Care Quality \(OHCQ\)](#)

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