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Performing CLIA Waived Tests in Maryland

To conduct CLIA-waived tests in Maryland, a laboratory must have a CMS CLIA Certificate of Waiver and either a [Maryland Laboratory Permit](#) or a Letter of Exception. All laboratories must follow the same CLIA-waived test requirements, including the requirement to follow the manufacturer's instructions for performing the test.

To add a new CLIA waived test to a Maryland Laboratory Permit or a Letter of Exception, the laboratory must complete a Change Form:

<https://health.maryland.gov/ohcq/Documents/Providers/Clinical-Labs/Forms/Lab-License-Change-Form.pdf>

CLIA waived tests on the Excepted list are on Schedule B of the Change Form. If a CLIA-waived test is not on the Excepted Test list, the applicant selects the test discipline under Schedule A. If help is needed with test selection please call 410-402-8025. [OHCQ](#) processes the request in 1 - 2 days.

The procedure to recommend the addition of new tests to the Excepted Test list, by review of the Laboratory Advisory Committee is in [COMAR 10.10.02.01\(E\)](#).

Office of Health Care Quality (OHCQ)

website: <https://health.maryland.gov/ohcq/Pages/home.aspx>

[Apply for a Maryland Clinical Lab License](#)