

CLIA Frequently Asked Questions:

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1. Does Virginia permit direct access testing? Yes, Section 8.01-581.18 of the Code of Virginia allows consumers to undergo medical testing without first obtaining an order for tests performed from their physician. The results of tests conducted without a physician's order shall be provided to the person who was the subject of the test. The test report should state in bold letters that: "it is the responsibility of the [test] recipient to arrange with his physician for consultation and interpretation of the results of such test."

2. Can the results of lab tests order by physicians be released directly to test subject? Yes, provided the lab receives written authorization from the physician ordering the test. Section 54.1-2409.4 of the Code of Virginia authorizes the release of test results to the test subject at the same time the results are provided to the physician.

3. When submitting a new application for CLIA certification, is it necessary to include the qualifications of the lab's director? Yes, the application should include proof of the lab director's qualifications, including any continuing education units (CEUs) taken by the lab director.

4. Who can qualify for a Provider Performed Microscopy (PPM) laboratory certificate? Under this certificate, select laboratory tests must be performed in an office setting, and be performed by a provider. A provider is a physician, dentist, or mid-level practitioner (nurse practitioner, physician's assistant, or nurse midwife). Mid-level practitioners must be authorized by the state to practice independently where the lab is located. The test specimens to be examined are limited to the microscopic examination of the following body fluids: urine, wet mounts including the presence/absence of bacteria, fungi, parasites; and human cellular elements in vaginal, cervical, and skin preparations. Nasal smears for granulocytes, fecal exams for leukocytes, and sperm qualitative analysis limited to the presence or absence of sperm and the detection of sperm motility are also performed under this certificate.

5. Sometimes my inspection is conducted several months before the certificates' expiration date. Why? The inspector may schedule your lab inspection up to 13 months before the expiration date of your certificate. The CLIA state inspectors schedule inspections according to location and expiration date in order for the inspections to be done in the most efficient manner.

6. Will the early inspection move my expiration date up and cost the lab more money? No. If your lab is inspected several months before its expiration date, your expiration date or fees will not change. The expiration date and the survey date are two separate fields in the computer database and are tracked separately. Although the inspection is completed months before the expiration date, the laboratory's new certificate will not be mailed until two weeks prior to the expiration date.

7. Can I reschedule my inspection? How much prior notification is given? A survey date can be rescheduled only if there is a serious illness, a death in the family or if the lab is forced to be closed on the day of the survey. CQHCCCP has recommended the inspector give the laboratory two weeks notice before an inspection. The laboratory should be prepared for an inspection at all times. If there is a complaint lodged against your laboratory, an unannounced inspection will occur. Your laboratory should maintain compliance with the regulations on an ongoing basis.

8. What should I do with the pre-inspection packet the laboratory received in the mail? Please review the accompanying correspondence and directions. All required documentation should be completed prior to the onsite inspection. The personnel form must be signed by the laboratory director. The lab will provide documentation of the highest level of education and of appropriate laboratory training for all new employees. This documentation must be reviewed by the CLIA inspector before the employee may perform any patient testing.

9. Where can I get a printed copy of the CLIA Federal regulation?

Superintendent of Documents
Government Printing Office
Attn: New Order
P.O. Box 371954
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Telephone: (202) 512-1800
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