

Frequently Asked Questions

What is a laboratory?

The CLIA definition of a laboratory is a facility that performs testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings. If you perform any testing as defined by CLIA, you are considered as having a laboratory or as a laboratory.

Who needs a CLIA certificate?

If a facility performs tests on materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings, you must apply for a CLIA certificate that corresponds to the complexity of tests performed.

The following are *some* examples that require a CLIA certificate:

- If clinical laboratory tests are performed.
- If testing and billing for the test (e.g., Medicare, Medicaid, private insurance, or the patient).
- If testing and not charging for the test.
- If the facility performing the test is a "hospital within a hospital."
- Performing grossing of a tissue specimen and reading of the smear.
- Performing only tissue grossing, dissection, orientation, mapping and inking.
- Performing only the professional part (reading/examination of the tissue smear).

I only perform medical procedures. Do I need a CLIA certificate?

No. Medical procedures that involve incisions with instruments performed to repair damage or arrest disease in a living body does not require a CLIA laboratory certificate.

What type of laboratory testing does NOT require a CLIA certificate?

- Any laboratory that only performs testing for forensic purposes and results not released for patient treatment.
- Any facility that only performs pre-employment drug screens and results are NOT used to send an employee to a treatment program.
- Research laboratories that test human specimens, but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, individual patients.
- Laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed that meets SAMHSA guidelines and regulations. However, a CLIA certificate is needed for all other testing conducted by a SAMHSA-certified laboratory.

Do I need a CLIA certificate to perform pre-employment drug screens?

If you are only doing pre-employment drug screens tests and test results are not used to send the employee to a treatment program, a CLIA certificate is not required.

Do I need a CLIA certificate to conduct health screening events?

Yes. Nebraska facilities must have a CLIA certificate and out-of-state facilities must be CLIA certified. Please inform the Nebraska State CLIA Program if you are conducting health fairs in Nebraska using a certificate issued by CMS from another State.