

CHAPTER 61-04-10 CLIA WAIVED LABORATORY TESTS

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61-04-10-01. Definitions.

For purposes of this chapter:

1. "CLIA" means the federal Clinical Laboratory Improvement Act of 1988, as amended.
2. "OSHA" means the federal occupational safety and health administration.

History: Effective December 1, 1999; amended effective April 1, 2016; January 1, 2024.

General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10(12)(14), 43-15-25.3

61-04-10-02. Education requirements for pharmacists or pharmacy technicians to perform CLIA waived laboratory tests.

A pharmacist and each pharmacy technician delegated must meet the following requirements in order to perform CLIA waived laboratory tests authorized by North Dakota Century Code section 43-15-25.3 or added to the list as allowed by section 61-04-10-06:

1. Successfully complete training and education that incorporates, at a minimum:
 - a. Infection control;
 - b. OSHA requirements;
 - c. Proper technique to collect laboratory specimens;
 - d. Recognized screening and monitoring values;
 - e. Quality control; and
 - f. The manufacturers' instructions for the waived tests being performed.

History: Effective December 1, 1999; amended effective April 1, 2016; January 1, 2024.

General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10(12)(14)(19), 43-15-25.3

61-04-10-03. Minimum quality standards required.

Pharmacists performing CLIA waived laboratory tests must meet the following standards:

1. Develop and maintain a policy and procedure manual that includes the following areas:
 - a. Quality control;
 - b. Infection control;

- c. Hazardous waste disposal;
- d. Recordkeeping; and
- e. Test result reporting.

History: Effective December 1, 1999; amended effective April 1, 2016.

General Authority: NDCC 28-32-02, 43-15-10

Law Implemented: NDCC 43-15-25.3

61-04-10-04. Proper CLIA registration.

The pharmacist-in-charge of a licensed pharmacy performing tests or any pharmacist operating in a facility not licensed by the board is responsible for ensuring that the location has a current CLIA waived certificate.

History: Effective December 1, 1999; amended effective April 1, 2016; January 1, 2024.

General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10(12)(14), 43-15-25.3

61-04-10-05. Notification of the board of pharmacy.

Repealed effective January 1, 2024.

61-04-10-06. Exempt tests and methods.

An individual licensed or registered by the board, performing the following food and drug administration-waived tests and using the following methods, is exempt from the provisions of North Dakota Century Code chapter 43-48:

1. Total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides test by any accepted method.
2. Any of the following tests by nonautomated or automated urinalysis by dipstick:
 - a. Bilirubin.
 - b. Blood.
 - c. Glucose.
 - d. Ketone.
 - e. Leukocyte.
 - f. Nitrate.
 - g. Potential of hydrogen (pH).
 - h. Protein.
 - i. Specific gravity.
 - j. Urobilinogen.
3. Fecal occult blood by any accepted method.
4. Ovulation test by visual color comparison.

5. Qualitative urine pregnancy test by visual color comparison.
6. Erythrocyte sedimentation rate by any accepted nonautomated method.
7. Whole blood glucose by any accepted single analyte method.
8. Spun microhematocrit by any accepted method.
9. Hemoglobin by single analyte instrument or manual copper sulfate method.
10. Any of the following tests by immunoassay using a rapid test device that detects antibodies or antigens:
 - a. Helicobacter pylori.
 - b. Influenza.
 - c. Mononucleosis.
 - d. Streptococcus group A.
 - e. Hepatitis C virus.
 - f. Respiratory syncytial virus.
11. Prothrombin time international normalized ratio by mechanical endpoint.
12. Antibodies to human immunodeficiency virus types 1 and 2.
13. Nicotine or cotinine test by urine.
14. Thyroid stimulating hormone test by blood.
15. Bone mass and bone mineral density test by any accepted method.
16. Drug screening tests by urine.

History: Effective April 1, 2016; amended effective January 1, 2024.

General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10(12)(14), 43-15-25.3

61-04-10-07. Delegation to registered pharmacy technicians.

Under the responsibility of the pharmacist-in-charge or pharmacist, a registered pharmacy technician may assist in performing CLIA waived laboratory tests. The registered pharmacy technician must have met the education requirements in section 61-04-10-02. The responsible pharmacist may not delegate the interpretation of the result of a CLIA waived test or clinical education of the patient to the registered pharmacy technician.

History: Effective January 1, 2024.

General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10(12)(14)(19), 43-15-25.3