CHAPTER 61-04-10
CLIA WAIVED LABORATORY TESTS

Section
61-04-10-01 Definitions
61-04-10-02 Education Requirements for Pharmacists to Perform CLIA Waived Laboratory Tests
61-04-10-03 Minimum Quality Standards Required
61-04-10-04 Proper CLIA Registration
61-04-10-05 Notification of the Board of Pharmacy
61-04-10-06 Exempt Tests and Methods

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.
3. "Portfolio review" means a review by the board of a pharmacist's records of ~~proficiency testing~~ training logs, control testing logs, and records of patient tests performed to determine that a pharmacist is continuously and consistently providing a service in a quality and competent manner.

History: Effective December 1, 1999; amended effective July 1, 2016.
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 43-15-25.3

61-04-10-02. Education requirements for pharmacists to perform CLIA waived laboratory tests. A pharmacist 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 ~~that~~ section 61-04-10-06:

1. Successfully complete ~~a board-approved course of study~~ training and education that incorporates ~~principles of general laboratory procedures to include~~, at a minimum:
   a. Infection control;
   b. OSHA requirements;
   c. Proper technique to collect laboratory specimens;
   d. Recognized screening and monitoring values; and
   e. Quality control.
   f. The manufacturers' instructions for the waived tests being performed.
2. Obtain and recertify the CLIA waived certificate every ~~three~~ two years ~~by portfolio review or reeducation~~.
3. ~~Successfully complete training for each specific instrument used to perform CLIA waived laboratory tests.~~

History: Effective December 1, 1999; amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 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 ~~procedural~~ manual that includes the following areas:
   a. Quality control;
   b. Infection control;
   c. Hazardous waste disposal;
   d. Recordkeeping; and
   e. Test result reporting.

~~2. Maintain participation in a nationally recognized proficiency program approved by the board.~~

History: Effective December 1, 1999; amended effective July 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 pharmacy performing the CLIA waived test ~~facility where the tests are performed~~ has a proper CLIA certificate.

History: Effective December 1, 1999; amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 43-15-25.3

61-04-10-05. Notification of the board of pharmacy. The pharmacist-in-charge of a licensed pharmacy that has obtained a CLIA certificate or any pharmacist operating in a facility not licensed by the board of pharmacy must notify the board prior to the initial performance of any CLIA waived tests. ~~The notification must specify the types of tests which are to be performed.~~

History: Effective December 1, 1999; amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 43-15-25.3

61-04-10-06. Exempt tests and methods. An individual licensed 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. Specifc 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 July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 43-15-25.3