



# CLIA BITS



North Dakota Department of Health  
Division of Health Facilities Fall 2006

## Important Notice from NDBCLP

Changes have been made regarding licensure exemption. Please note the tests unlicensed individuals can perform and the supervision of testing individuals. The North Dakota Board of Clinical Laboratory Practice has requested the following notice be included in CLIA Bits.

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**CHAPTER 96-02-10**

### EXEMPTION FROM LICENSURE

#### Section

- 96-02-10-01 Exempt tests and Methods  
96-02-10-02 Supervision

**96-02-01. Exempt Tests and Methods.** An individual, supervised by an individual licensed by the board, performing the following tests and using the following methods, is exempt from the provisions of North Dakota Century Code chapter 43-48:

1. Non-automated urinalysis by dipstick or tablet color comparison.
2. Fecal occult blood by an accepted method.
3. Ovulation test by visual color comparison.
4. Qualitative urine pregnancy test by visual color comparison
5. Erythrocyte sedimentation rate by any accepted non-automated method.
6. Whole blood glucose by any accepted single analyte method.
7. Spun microhematocrit by any accepted method.
8. Hemoglobin by single analyte instrument of manual copper sulfate method.

**History:** Effective January 1, 2006.

**General Authority:** NDCC 43-48-03, 43-48-04

**Law Implemented:** NDCC 43-48-03.

**96-02-10-02. Supervision.** As used in subsection 9 of North Dakota Century Code section 43-48-03 and section 96-02-10-01, "supervised" means the following:

1. The supervisor shall identify the individuals being supervised on a form provided by the board, and shall promptly notify the board of any changes to the information provided.
2. The supervisor shall ensure the individuals being supervised are appropriately trained in all tests and methods performed by the supervised individuals.
3. The supervisor shall:
  - a. Perform annual competency assessments of the individuals supervised using generally accepted clinical laboratory standards.
  - b. Not allow an individual supervised to start or continue performing tests until the individual has been properly trained and demonstrated competency.
  - c. Document training and competency assessments, retain the documentation for three years, and submit the documentation to the board upon request.
4. The supervisor shall regularly monitor and be available to consult with the individuals being supervised.

Failure by the licensee to supervise is unprofessional conduct and may be subject to disciplinary action by the board.

**History:** Effective January 1, 2006.

**General Authority:** NDCC 43-48-04

**Law Implemented:** NDCC 43-48-03

## NEW: Online post survey evaluation questionnaire

The Division of Health Facilities has developed a new post survey evaluation questionnaire. Previously, the laboratory was given a paper state evaluation form at the conclusion of the CLIA survey to be completed and sent to our office. As of August 1, 2006, laboratories will be given the opportunity to complete the Post Survey Evaluation Form online. A letter will be sent to the laboratory after an acceptable plan of correction has been received. Laboratories with no deficiencies will also receive a letter. The letter will provide instructions on how to access the online post survey evaluation and an authentication code. If a laboratory does not have internet access, an alternative evaluation is available. We appreciate the laboratories' feedback as a source to improve our quality.

### Interpreting Manufacturer's Instructions for Waived Testing

If the manufacturer's instructions include the words "always", "require", "shall", or "must", the laboratory is required to follow the instructions. If the manufacturer's instructions include the words

"recommend" or "should", it would be good laboratory practice to follow the instructions, but not required for waived testing. For non-waived testing you must follow the manufacturer's instructions or the CLIA requirements, whichever are more stringent.

### Quality Control Reminders

**Gram stain quality control** - The regulations state the laboratory must check for positive and negative reactivity using control organisms each week for Gram stains (493.1261(a)(2)). Remember to check the manufacturer's requirements as some require daily QC. The laboratory must follow the more stringent requirements.

**Hemocytometer manual cell count quality control** - For manual cell counts performed using a hemocytometer, one level of control material must be tested each 8 hours of testing. Patient specimens and controls must be tested in duplicate (493.1269(a)). Control materials need to be of similar matrix to the patient specimens.

**Histopathology and Cytology quality control documentation** - Fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For

differential and special stains, a control slide of known reactivity must be stained with each group of slides. The reactions must be documented (493.1273). Placing a check mark next to control indicates the control was performed, but does not record the positive and negative reactivity. Make sure the positive and negative reactivity is documented.

**Specific gravity by refractometer quality control** - Since this is a non-waived test, two levels of control material must be tested each day of patient testing. Checking distilled water daily for 1.000 value is a calibration function, so distilled water cannot be used as a control.



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