## STIA ALTS

## **Most Commonly Cited Deficiencies**

Following is a breakdown of the most common deficiencies cited in the North Dakota CLIA program from Oct. 1, 2011, through Sept. 30, 2012.

**D5439** — Calibration Verification. Calibration verification must be performed at least once every six months. See CLIA regulations at 493.1255(b) for more details.

**D5805** — Test Report. The test report must include the following: Patient's name and identification number or unique patient identifier and identification number, name and address of the laboratory location where the test was performed, test report date, test performed, specimen source (when appropriate), test result and units of measurement or interpretation, and information regarding the condition and disposition of specimens that do not meet criteria for acceptability.

**D6087** — Laboratory Director Responsibilities. The laboratory director must ensure laboratory personnel perform the test methods as required for accurate and reliable results.

**D2009** — Testing of Proficiency Samples. The individual testing the proficiency samples and the laboratory director must attest the proficiency samples were tested in the same manner as patient specimens.

**D2016** — Successful Participation in Proficiency Testing. Each laboratory performing non-waived testing must successfully participate in an approved proficiency testing program.

**D5401** — Procedure Manual. A written procedure manual for all tests performed by the laboratory must be available to and followed by laboratory personnel.

**D5413** — Test Systems, Equipment, Instruments, Reagents, Materials, and Supplies. Reagents, solutions, culture media, control materials and other supplies must not be used when they have exceeded their expiration date, have deteriorated or are of substandard

quality.

**D5421** — Establishment and Verification of Performance. Each laboratory that introduces a test method must demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: accuracy, precision and reportable range of test results. The laboratory also must verify over time

(Continued on page 2)

## **Inside this issue:**

Most Commonly Cited Deficiencies	1, 2
The Clinical Consultant's Role in the Laboratory	2

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## The Clinical Consultant's Role in the Laboratory

The clinical consultant must be a physician or a qualified laboratory director with a doctoral degree. The clinical consultant's responsibility in

the laboratory is to provide consultation regarding the appropriateness of the testing ordered and the interpretation of the test results. The clinical consultant must be available to provide consultation to the laboratory's clients and to

assist the clients in ensuring that appropriate tests are ordered to meet the clinical expectations. The clinical consultant should review reports to ensure that test results include patient information required for interpretation of specific patient conditions. The laboratory must ensure the clinical consultant is available to consult and communicate with the laboratory's clients on matters related to the quality of test results reported and their interpretation.



Sources: Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services.

(Continued from page 1) Most Commonly Cited Deficiencies

that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

**D5447** — Control Procedures. For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process.

D5481 — Control Procedures. Results of control material must meet the laboratory's and the manufacturer's criteria for acceptability before reporting patient results. The control results must be documented.

**D5551** — Immunohematology. The laboratory must perform ABO grouping, D typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions.

D6053/D6127 — Technical Consultant/Technical Supervisor Responsibilities. The technical consultant/technical supervisor is responsible for evaluating and documenting the performance of moderate/high complexity testing personnel at least semiannually during the first year.

**D6054/D6128** — Technical Consultant/Technical Supervisor Responsibilities. The technical consultant/technical supervisor is responsible for evaluating and documenting the performance of moderate/high complexity testing personnel at least annually.







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Page 2 CLIA BITS