### 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:

<table>
<thead>
<tr>
<th>Most Commonly Cited Deficiencies</th>
<th>1, 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Clinical Consultant’s Role in the Laboratory</td>
<td>2</td>
</tr>
</tbody>
</table>

**If you would like to receive CLIA Bits electronically, please send your e-mail address and company name to Bridget Weidner at bweidner@nd.gov.**
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.