

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2108574	(X3) Date Survey Completed 03/16/2018
Name of Provider or Supplier Lower Sioux Health Care Center	Street Address, City, State 39648 Reservation Highway 3, Morton, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to establish a written competency assessment procedure which included the following requirements found in Subpart M. 493.1451 (b)(8)(i) Direct observation of routine test performance; (b)(8)(ii) Monitoring the recording and reporting of test results; (b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records; (b)(8)(iv) Direct observation of performance of instrument maintenance and function checks; (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and (b)(8)(vi) Assessment of problem solving skills. Findings are as follows: 1. The laboratory performed Chemistry, Hematology, and Microbiology testing as confirmed by Testing Personnel 1 (TP-1) during a tour of the laboratory on 3/16/18 at 9:05 a.m. 2. A competency assessment procedure was not found during review of laboratory policies and procedures. The laboratory was unable to provide a competency assessment procedure upon request. 3. In an interview on 3/16/18 at 10:00 a.m., TP-1 confirmed the above finding. .</p>
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests</p>

and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to ensure accurate reference ranges were listed on Chemistry final test reports. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP-1) during a tour of the laboratory on 3/16/18 at 9:05 a.m.. 2. Reference range discrepancies were revealed during review of test procedures and patient test reports for the following tests: - Chloride: The Abaxis Picollo Comprehensive Metabolic Panel (CMP) SOP, located in the Laboratory Procedures manual, listed the Chloride reference range = 98-108 mEQ/L. A final Test Report, performed 12/29/2016 on a Female/73 years, listed the Chloride reference range = 97-107 mEQ/L. - TSH The Qualigen FastPack TSH IP Package Insert listed, reviewed on-line, listed the TSH reference range = 0.66 - 5.45 uIU/mL. A final Test Report, performed 1/11/2017 on a Female/29 years, listed the TSH reference range = 0.66 - 5.45 units/ mL. 3. In an interview on 3/16/18 at 2:0 p.m., TP-1 confirmed the above finding. .

D5821

TEST REPORT

CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to establish and follow a written corrected reports procedure. Findings are as follows: 1. The laboratory performed Chemistry, Hematology, and Microbiology testing as confirmed by Testing Personnel 1 (TP-1) during a tour of the laboratory on 3/16/18 at 9:05 a.m. 2. A corrected reports procedure was not found during review of laboratory policies and procedures. The laboratory was unable to provide a corrected reports procedure upon request. 3. In an interview on 3/16/18 at 10:50 a.m., TP-1 confirmed the above finding. .

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the Technical Consultant (TC) failed to assess the competency of 2 of 2 new Testing Personnel at least twice annually during the first year of testing. Findings are as follows: 1. The laboratory performed Chemistry, Hematology, and Microbiology testing as confirmed

by Testing Personnel 1 (TP-1) during a tour of the laboratory on 3/16/18 at 9:05 a.m. 2. The laboratory commenced operations in June, 2016. Testing Personnel 1 & 2 (TP-1 & TP-2) were listed on Form CMS-209 Laboratory Personnel Report (CLIA) as employees performing moderate complexity testing. Laboratory records indicated TP-1 received Initial Training in March, 2016, and TP-2 received Initial Training in June, 2016. 3. Semi-annual competency assessments for TP-1 and TP-2 were not found during review of laboratory records. The laboratory was unable to provide the required documentation upon request. 4. In an interview on 3/16/18 at 10:00 a.m., the TC confirmed the above finding. . .