

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0410720	(X3) Date Survey Completed 11/09/2021
Name of Provider or Supplier Deer Lodge Medical Center	Street Address, City, State 1100 Hollenback Lane, Deer Lodge, MT	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: . Based on record review of American Proficiency Institute (API) and American Association of Bioanalysts (ABB) proficiency testing scores for Hematology and interview with Technical Supervisor (TS) #1, the laboratory failed to ensure the laboratory was enrolled in a HHS-approved proficiency testing program for Hematology (Reticulocyte counts) performed on the Sysmex CA-600 for years 2020 and 2021. Findings: 1. Review of American Proficiency Institute (API) and American Association of Bioanalysts (ABB) proficiency testing scores for Hematology lacked results for Reticulocytes Counts. 2. Review of 2021 Test Volume Sheet revealed 18 Reticulocytes Counts were performed. 3. Interview with TS #1 on November 9, 2021 at 10:00 AM, confirmed the laboratory failed to be enrolled in a HHS-approved proficiency testing program for Hematology (Reticulocyte counts) performed on the Sysmex CA-600 for years 2020 and 2021.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the</p>

laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
 Based on review of chemistry and hematology calibration records and interview with the Technical Supervisor (TS) #1, the laboratory failed to perform at least three-point (a minimal, mid-point, and maximum) calibration verification every six months or after CLEW software updates for the Abbott i-STAT Analyzer and failed to verify sodium citrate tubes every 6 months to achieve platelet poor plasma from January 2020 to November 2021. Findings: 1. Review of 2020 and 2021 calibration records for Abbott i-STAT analyzer for analytes sodium, potassium, chloride, bicarbonate, blood urea nitrogen, creatinine, calcium, and glucose revealed the laboratory failed to perform a calibration verification including, at least, a minimal, midpoint, and maximum value for each analyte, performed every six months or after CLEW software updates. 2. No platelet poor plasma studies using sodium citrate tubes were available for review from January 2020 to November 2021. 3. Interview with the TS #1 on November 9, 2021 at 1:50 PM, confirmed the laboratory failed to perform at least a three-point calibration verification for analytes performed on the i-STAT Analyzer every six months or after CLEW software updates and failed to verify sodium citrate tubes every 6 months to achieve platelet poor plasma from January 2020 to November 2021.

D5775

COMPARISON OF TEST RESULTS
 CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
 Based on record review of instrument comparison documentation and interview with Technical Supervisor (TS) #1, the laboratory failed to evaluate and define the relationship between test results using different instruments from January 2020 to

November 2021 for analyzers Abbott i-STAT and the Siemens Dimension EXL for analytes sodium, potassium, chloride, bicarbonate, blood urea nitrogen, creatinine, calcium and glucose; analyzers bioMrieux VIDAS and PATHFAST for analyte D-Dimer; and analyzers Siemens Dimension EXL and PATHFAST for analyte troponin two times a year. Findings: 1. No instrument comparison studies for Abbott i-STAT and the Siemens Dimension EXL for analytes sodium, potassium, chloride, bicarbonate, blood urea nitrogen, creatinine, calcium and glucose were available to review from January 2020 to November 2021. 2. No instrument comparison studies for bioMrieux VIDAS and PATHFAST for analyte D-Dimer were available to review from January 2020 to November 2021. 3. No instrument comparison studies for Siemens Dimension EXL and PATHFAST for analyte troponin were available to review from January 2020 to November 2021. 4. Interview with TS #1 on November 9, 2021 at 3:18 PM, confirmed the laboratory failed to evaluate and define the relationship between test results using different instruments from January 2020 to November 2021, for analyzers Abbott i-STAT and the Siemens Dimension EXL for analytes sodium, potassium, chloride, bicarbonate, blood urea nitrogen, creatinine, calcium and glucose; analyzers bioMrieux VIDAS and PATHFAST for analyte D-Dimer; and analyzers Siemens Dimension EXL and PATHFAST for analyte troponin.