

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D2102074	<b>(X3) Date Survey Completed</b>  02/17/2022
<b>Name of Provider or Supplier</b>  Big Sky Medical Center	<b>Street Address, City, State</b>  334 Town Center Ave, Big Sky, MT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> 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 and interview with Testing Personnel (TP) #1, the laboratory failed to ensure the laboratory was enrolled in an HHS-approved proficiency testing program for Chemistry (C-Reactive Protein (CRP)) from January 1, 2020 to December 31, 2021. Findings: 1. Review of Test Volume Report revealed 175 CRP tests were performed for 2021. 2. Review of 2020 and 2021 American Proficiency Institute (API) Testing Program records lacked documentation of proficiency testing for CRP. 3. Interview on February 17, 2022 at 3:30 PM with the TP#1 confirmed the laboratory failed to enroll in an HHS-approved proficiency testing program for CRP from January 1, 2020 to December 31, 2021.</p>
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the 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)</p>

-- (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 calibration records for the Abbott i-STAT Analyzer using EG7+ and CHEM 8+ cartridge for analytes sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, total carbon dioxide, pH, PCO<sub>2</sub>, and PO<sub>2</sub> and interview with the Testing Personnel (TP) #1, the laboratory failed to perform at least a three-point (a minimal, mid-point, and maximum) calibration verification every six months or after CLEW software updates for years 2020 and 2021. Findings: 1. Review of 2020 and 2021 calibration records for Abbott i-STAT analyzer lacked documentation of a calibration verification including, at least, a minimal, midpoint, and maximum value for each analyte performed every six months or after CLEW software updates for years 2020 and 2021. 2. Interview with the TP #1 on February 17, 2021 at 10:30 AM, 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 for years 2020 and 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 and interview with testing personnel (TP)#1, the laboratory failed to regularly perform instrument comparison for chemistry analyzers Dimension EXL 200 and Abbott iSTAT testing analytes sodium, potassium, chloride, ionized calcium, total CO (2), glucose, blood urea nitrogen (BUN) and creatinine from February 17, 2020 to February 17, 2022 Findings: 1. Interview with TP#1 on February 17, 2022 at 9:50 AM revealed the Abbott iSTAT analyzer was used as a backup chemistry analyzer using the CHEM 8+ cartridge. 2. Review of laboratory instrument comparison for 2020 and 2021 revealed the laboratory failed to perform and document comparison studies twice a year for Dimension EXL 200 and Abbott iSTAT analyzers performing sodium, potassium, chloride, ionized calcium, total CO (2), glucose, blood

urea nitrogen (BUN) and creatinine analyte. 3. Interview with TP#1 on February 17, 2022 at 10:00 A.M., confirmed the laboratory failed to regularly perform twice a year instrument comparison between Dimension EXL 200 and Abbott i-STAT testing analytes sodium, potassium, chloride, ionized calcium, total CO (2), glucose, blood urea nitrogen (BUN) and creatinine from February 17, 2020 to February 17, 2022.