Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0689518	07/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Wheatland Memorial Healthcare Laboratory	530 3rd Street Northwest, Harlowton, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of verification records, laboratory procedures, and an interview with general supervisor (GS) #1, the laboratory failed to verify precision over time, reportable range, and the manufacturer's normal reference ranges were appropriate for the laboratory's patient population prior to the laboratory director's approval from February 16, 2023, to July 24, 2024. Findings: 1. The laboratory failed to provide verification studies to verify the miniiSED's automated erythrocyte sedimentation rate (ESR) reportable range (1 to 130 mm/hr) and the manufacturer's normal reference ranges were appropriate for the laboratory's patient population prior to the laboratory director's final approval on May 18, 2023. 2. The laboratory failed to assess the repeatability of day-to-day variance and verify the normal reference ranges of Siemens Dimension EXL's analytes: N-terminal fragment of brain natriuretic peptide (NT-proBNP) (approved 11/14/23), glycated hemoglobin (HbA1c) (approved 10/30/23), and vancomycin (approved 2/16/23) were appropriate for the laboratory's patient population prior to the laboratory director's approval dates. 3. Based on the test volume sheet, 132 ESR, 21 NT-proBNP, and 236 HbA1c patient tests were performed in the last 12 months. 4. The laboratory failed to provide a procedure to address how the laboratory verifies the performance of new assays, instruments, or methods. 5. An interview with GS #1 on July 24, 2024, at 10:30 AM confirmed the laboratory failed

	to perform studies to either verify the reportable testing range, precision over time, or the manufacturer's normal reference ranges for analytes NT-proBNP, HbA1c, and vancomycin performed on the Siemens Dimension EXL and the automated miniiSed for ESR from February 16, 2023, to July 24, 2024.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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) -- (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: REPEAT DEFICIENCY Cited previously on recertification survey dated April 26, 2021. Based on review of the calibration records, manufacturer's instructions, and interview with general supervisor (GS) #1, the laboratory failed to perform at least three-point (a minimal, mid-point, and a maximum) calibration verification every six months for sodium, potassium, chloride, and triglycerides from July 24, 2022, to July 24, 2024. Findings: 1. A review of the Siemens Dimension EXL 200 chemistry analyzer calibration records for triglycerides, sodium, potassium, and chloride lacked calibration verification records from July 24, 2022, to July 24, 2024. 2. An interview with GS #1 on July 24, 2024, at 10:30 AM confirmed the laboratory failed to perform at least a three-point calibration verification that covers the manufacturer's reportable range every six months for sodium, potassium, chloride, and triglycerides performed on the Siemens Dimension EXL 200 chemistry analyzer from July 24, 2022, to July 24, 2024.
D5535	ROUTINE CHEMISTRY CFR(s): 493.1267(a)(d) For blood gas analyses, the laboratory must perform the following: (a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer. (d) Document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on a review of blood gas records, OPTI CCA-TS Operator's Manual, and an interview with General Supervisor (GS) #1, the laboratory failed to perform at least three-point (a minimal, mid-point, and maximum) calibration verification every six months per the manufacturer's instructions from July 24, 2022, to July 24, 2024. Findings: 1. No records of calibration verification studies performed every six months were available for review. 2. Review of the OPTI CCA-TS Operator's Manual revealed "4.4 Calibration Verification ... may be required by various regulatory agencies." 3. Based on the test volume sheet, 20 patient tests were performed for analytes pH, pCO2, and pO2 from July 24, 2023, to July 24, 2024. 4. Interview with the GS #1 on July 24, 2024, at 11:30 AM, confirmed the laboratory failed to perform calibration verification every six months on the OPTI CCA-TS Blood Gas Analyzer from July 24, 2022, to July 24, 2024.