Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0056312	08/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
North Big Horn Hospital District	1115 Lane 12, Lovell, WY	

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	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, review of personnel records, policy and procedure review, and staff interview, the laboratory failed to ensure the technical supervisor and general supervisor's competency assessmenst were completed for 1 of 2 years (2021) reviewed. The findings were: 1. Review of the CMS 209 Laboratory Personnel Report showed the laboratory employed one staff member which performed the duties of the technical supervisor (TS) and the general supervisor. The following concerns were identified: a. Review of the technical supervisor/general supervisor's personnel record showed no evidence a competency assessment had been completed in 2021. b. Interview with the TS on 8/9/22 at 10:10 AM confirmed a competency assessment had not been completed in 2021. c. Review of the policy and procedure titled "Laboratory Testing Staff Competency", last reviewed 6/2/22, failed to include a procedure for assessing the competency of the technical supervisor and the general supervisor. d. Review of the policy and procedure titled "Delegation of Duties", issued on 5/2/22, showed the laboratory director was responsible for the assessment of technical supervisor/consultant responsibilities and competency and the "Technical Supervisor/consultant" was responsible for the assessment of the general supervisory tasks.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation, review of the immunohematology records, lack of documentation, review of the Thermo Fisher Centra W cell washer/centrifuge operator's manual, and staff interview, the laboratory failed to follow the manufacturer's instructions to perform centrifuge and cell washer revolutions per minute (RPM) and timer checks every three months for 2 of 2 years (2021, 2022) reviewed. The laboratory performed approximately 111 immunohematology patient tests per year. The findings were: 1. Observation of the Centra W cell washer /centrifuge showed a maintenance sticker which showed the RPM and timer was checked 4/2022 and noted the next maintenance was due 4/2023. The previous years maintenance stickers were not visible. 2. Review of the immunohematology records showed no evidence the Centra W cell washer/centrifuge RPM and timer had been checked every 3 months as required. 3. Review of the Thermo Fisher Centra W cell washer/centrifuge operator's manual retrieved at https://assets.thermofisher.com/TFS-Assets/LED/manuals/D21694~.pdf on 8/13/22 specified RPM and speed function be checked once every 3 months. 4. Interview with the technical supervisor on 8/9/22 at 3:59 PM confirmed the corrective action to correct the prior deficiency had not been completed. THIS IS A REPEAT DEFICIENCY, last cited on 9/1/20.
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: Based on lack of documentation, review of the Abbott iSTAT manufacturer's instructions, and staff interview, the laboratory failed to verify the reportable range at least every 6 months using testing materials with values at the zero or minimal level,

	the mid-level, and the upper-level of the reportable range for the CHEM8+ test cartridge (sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, total carbon dioxide, hematocrit, and hemoglobin), the CG4+ test cartridge (pH, partial pressure of oxygen, partial pressure of carbon dioxide, and the Troponin I test cartridge analyzed on the Abbott i-STAT instrument for 2 of 2 years of testing (2021, 2022) reviewed. The laboratory performed approximately 650 patient tests annually using the Abbott iSTAT instrument. The findings were: 1. Review of the laboratory's records showed no documentation the reportable range of the analytes tested on the Abbott i-STAT instrument had been verified. 2. Review of the Abbott i-STAT manufacturer's instructions, last revised 2/26/20, showed "Calibration verification procedure is intended to verify the accuracy of results over the entire measurement range of a test as may be required by regulatory or accreditation bodies." 3. Interview with the technical supervisor on 8/9/22 at 2:42 PM confirmed the calibration verification studies had not been completed.