Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410720	06/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Deer Lodge Medical Center	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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) and American Association of Bioanalysts (AAB) proficiency testing records and an interview with the technical supervisor (TS) #1, the laboratory failed to have an attestation form signed by testing personnel and the laboratory director to attest to the routine integration of the samples into the patient workload using the laboratory's routine methods for six of six proficiency testing events from June 17, 2023, to June 18, 2025. Findings: 1. Review of proficiency testing records failed to have an Attestation Statement for the following proficiencies: API 2024 Hematology/Coagulation 1st Event AAB 2024 Urine Drug Screen 2nd Event AAB Viral Markers 2024 1st Event AAB Blood Gases 2024 1st Event AAB Infectious Mono 2024 3rd Event AAB Blood Cell Identification 2024 3rd Event 2. An interview with TS #1 on June 17, 2025, at 4:00 PM confirmed the laboratory failed to have an attestation form signed by testing personnel and the laboratory director to attest to the routine integration of the samples into the patient workload using the laboratory's routine methods for six of six proficiency testing events from June 17, 2023, to June 18, 2025.
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 a record review and an interview with technical supervisor (TS) #1, the laboratory failed to include in its procedure and the general supervisor' competency assessment criteria, failed to perform the competency assessment for six of the six general supervisors (GS) listed on the CMS-209 Personnel Report form and failed to follow its procedure to annually assess five of the five testing personnel (TP) for each specific test procedure they perform using the six competency assessment procedures from June 17, 2023, to June 18, 2025. Findings: 1. A review of the CMS-209 Personnel Report Form revealed six of the six personnel listed as general supervisors (GS #1, GS #2, GS #3, GS #4, GS #5, and GS #6) lacked a competency assessment based on the position responsibilities from June 17, 2023, to June 18, 2025. 2. A review of the "Laboratory Competency Assessments" procedure lacked the frequency of the general supervisor competency assessment based on their federal regulatory responsibilities. 3. The laboratory failed to follow its "Laboratory Competency Assessments" procedure and assess the competency of TP #1, TP #3, TP #4, TP #5, and TP #6 annually for each test procedure they performed using the six competency assessment procedures from June 17, 2023, to June 18, 2025. 4. An interview with TS #1 on June 17, 2023, at 12:30 PM confirmed that the laboratory failed to include in its procedure the general supervisor' competency assessment criteria, failed to perform the competency assessment for six of the six general supervisors, and failed to follow its procedure to annually assess five of the five testing personnel for each specific test procedure they perform using the six competency assessment procedures from June 17, 2023, to June 18, 2025.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) proficiency testing records and an interview with the technical supervisor (TS) #1, the laboratory failed to verify the accuracy of "Not Graded" scores for four of the four proficiency testing (PT) events from June 17, 2023, to June 18, 2025. Findings: 1. A review of proficiency testing records lacked documentation that the laboratory verified the accuracy of the "Not Graded" scores for the following PT events: API 2024 Hematology/Coagulation - 3rd Event for Body Fluid Cell Count-C sample BFC-03 API 2024 Microbiology - 1st Event for Gram Stain Morphology sample GS-02 API 2024 Microbiology - 2nd Event for Gram Stain sample GS-08 API 2024 Microbiology - 3rd Event for Gram Stain sample GS-13 2. An interview with TS #1 on June 17, 2025, at 4:10 PM confirmed the laboratory failed to verify the accuracy of "Not Graded" scores for four of the four PT events from June 17, 2023, to June 18, 2025.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the microbiology procedure manual, testing records, and an interview with the technical supervisor (TS) # 1, the laboratory lacked step-by-step instructions for performing wound cultures from June 17, 2023, to June 18, 2025. Findings: 1. A review of microbiology procedures lacked step-by-step instructions for performing wound cultures. A review of the test volume sheet revealed the laboratory performed 1200 patient cultures in the last 12 months. 2. An interview with TS #1 on June 18, 2025, at 3:20 PM, confirmed that the laboratory procedures lacked step-by-step instructions for performing wound cultures from June 17, 2023, to June 18, 2025.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedures and an interview with technical supervisor (TS) # 1, the laboratory procedures lacked the current laboratory director's signature and date for approval from July 13, 2023, to June 18,2025. Findings: 1. A review of the laboratory's procedure revealed that the hematology, urinalysis, drug screen, and coagulation procedures as well as the instrument manuals for the MiniiSed, Stat Profile Prime Plus, and VIDAS, did not have the current laboratory director's signature and date of approval. 2. An interview with TS #1 on June 18, 2025, at 5:30 PM, confirmed that the procedure manuals and instrument manuals lacked the current laboratory director's signature and date of approval from July 13, 2023, to June 18, 2025.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those

	established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 patient results' reports, verification studies, and an interview with the technical supervisor (TS) #1, the laboratory failed to verify the performance specifications comparable to those established by the manufacturer for three out of three platforms before reporting patient test results from June 17, 2023, to June 18, 2025. Findings: 1. The laboratory failed to verify the precision, analytical measurement range, and that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting patient test results for erythrocyte sedimentation rate (ESR) performed on the ALCOR miniiSED. 2. The laboratory failed to verify precision over time and ensure the reference intervals (normal values) are appropriate for the laboratory's patient population before reporting patient test results for pH, Potassium (K), Blood Urea Nitrogen (BUN), Partial Pressure of Carbon Dioxide (pCO2), Chloride (Cl), Total Hemoglobin (tHb), Partial Pressure of Oxygen (pO2 ,) Ionized Calcium (iCa,) Oxyhemoglobin (O2 Hb), Oxygen Saturation (SO2 %), Ionized Magnesium (iMg), Carboxyhemoglobin (COHb), Hematocrit (Hct), Glucose (Glu), Methemoglobin (MetHb), Sodium (Na), Lactate (Lac), Deoxyhemoglobin (HHb), Creatinine (Creat) performed on the Stat Profile Prime Plus analyzer. 3. The laboratory failed to verify precision over time and that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population for Glial Fibrillary Acidic Protein (GFAP) and Ubiquitin Carboxyl-terminal Hydrolase L1 (UCH-L1) performed on the VIDAS system before reporting patient test results. 4. An interview with TS #1 on June 18, 2025, at AM, confirmed the laboratory failed to verify the performance specifications comparable to those established by the manufacturer for three out of three testing platforms before reporting patient test results from June 17, 2023, to June 18, 2025.