Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0519922	04/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lander Medical Clinic	745 Buena Vista Dr, Lander, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 proficiency testing record review and staff interview, the laboratory failed to ensure all of the proficiency testing specimens within a specialty or subspecialty received during an event were analyzed by one analyst for 10 of 20 proficiency testing events (Chemistry, Microbiology) reviewed from April 2022 to April 2024. In addition, the laboratory failed to rotate testing personnel for 3 of 3 Miscellaneous Chemistry testing events reviewed. The findings were: 1. Review of the 2022 American Proficiency Institute (API) attestation statements for Chemistry and Microbiology Event #2 and Event #3 were signed as tested by both the technical consultant (TC) and TP (testing personnel) #1. 2. Review of the 2023 API attestation statements for Chemistry Event #1, #2, and #3 and Microbiology Event #3 were signed as tested by both the TC and TP #1. 3. Review of the 2024 API attestation statements for Chemistry Event #1 and Microbiology Event #1 were signed as tested by both the TC and TP #1. 4. Review of the API 2022 Miscellaneous Chemistry Event #2 and the 2023 Miscellaneous Chemistry Event #1 and #2 showed no evidence TP #1 had participated in the testing event. 5. Interview with the TC on 4/10/24 at 1:38 PM confirmed the proficiency testing specimens were not assigned to one testing personnel per event and not rotated as required.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination,

	and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and staff interview, the laboratory failed to maintain a copy of the American Proficiency Institute (API) proficiency testing data submission forms for 18 out of 20 testing events reviewed from April 2022 to April 2024. The findings were: 1. Review of the laboratory's proficiency testing records from April 2022 to April 2024 showed 18 out of the 20 events failed to include the data submission forms. 2. Interview with the technical consultant on 4/10 /24 at 1:30 PM confirmed the proficiency testing records failed to include a copy of the data submission forms.
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) 209 Laboratory Personnel Report, review of personnel records and staff interview, the laboratory failed to ensure the technical consultant's competency assessment had been completed for 2 of 2 years reviewed (2022, 2023). The findings were: 1. Review of the CMS 209 Laboratory Personnel Report showed 1 technical consultant (TC) was listed for the specialties of microbiology, hematology, and chemistry. 2. Review of the personnel files for the TC showed no documentation a competency assessment had been completed in 2022 or 2023. 3. The laboratory was unable to locate a competency assessment policy and procedure. 4. Interview with the TC on 4/10/24 at 1:38 PM confirmed the required competency assessments had not been completed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, staff interview, and policy and procedure review, the laboratory failed to review and evaluate proficiency testing (PT) results for 8 of 20 proficiency testing events reviewed between April 2022 and April 2024. The findings were: 1. Review of the American

	Proficiency Institute (API) 2022 Chemistry Event #2 PT records showed the laboratory scored an 80% on measured LDL (low density lipoprotein). There was no documentation the laboratory had evaluated the proficiency testing results. 2. Review of the API 2022 Hematology Event #2 PT records showed the laboratory scored an 80% on the eosinophil count. There was no documentation the laboratory had evaluated the proficiency testing results. 3. Review of the API 2022 Hematology Event #3 PT records showed the laboratory scored an 80% on the lymphocyte count. There was no documentation the laboratory had evaluated the proficiency testing results. 4. Review of the API 2023 Chemistry Event #1 PT records showed the laboratory scored an 80% on albumin. There was no documentation the laboratory had evaluated the proficiency testing results. 5. Review of the API 2023 Chemistry Event #2 PT records showed the laboratory scored an 80% on measured LDL. There was no documentation the laboratory had evaluated the proficiency testing results. 6. Review of the API 2023 Hematology Event #1 PT records showed the laboratory scored an 80% on hematocrit and the blood cell identification. There was no documentation the laboratory had evaluated the proficiency testing results. 7. Review of the API 2023 Hematology Event #2 PT records showed the laboratory scored an 80% on blood cell identification. There was no documentation the laboratory had evaluated the proficiency testing results. 8. Review of the 2024 API Chemistry Event #1 PT records showed the laboratory scored an 80% on phosphorus. There was no documentation the laboratory had evaluated the proficiency testing results. 9. Interview with the technical consultant on 4/10/24 at 1:38 PM confirmed an evaluation of the proficiency testing results had not been evaluated. 10. Review of the "Proficiency Testing Guidelines" policy, last reviewed May 2022, showed "Survey performance resulting in a score of less than 100% will require further investigation and correction...Any analyte that fails evaluation against graded criteria should be re-evaluated to identify the reason for the failure and corrective action."
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, staff interview, and review of policy and procedure, the laboratory failed to review proficiency test results that received an artificial score of 100% due to lack of peer group consensus for 5 of 20 American Proficiency Institute (API) proficiency testing events reviewed from April 2022 through April 2024. The findings were: 1. Review of the 2022 API Hematology Event #2 proficiency testing comparative evaluation form showed the laboratory received an artificial score of 100% for the microscopic vaginal wet prep. There was no documentation the laboratory had performed a self-evaluation. 2. Review of the 2022 API Hematology Event #2 proficiency testing comparative evaluation form showed the laboratory received an artificial score of 100% on the blood cell identification challenge. There was no documentation the laboratory had performed a self-evaluation. 3. Review of the 2023 API Chemistry Event #2 proficiency testing comparative evaluation form showed the laboratory received an artificial score of 100% on Troponin I. There was no documentation the laboratory

	had performed a self-evaluation. 4. Review of the 2023 API Hematology Event #3 proficiency testing comparative evaluation form showed the laboratory received an artificial score of 100% for the microscopic vaginal wet prep. There was no documentation the laboratory had performed a self-evaluation. 5. Review of the 2024 API Chemistry Event #1 proficiency testing comparative evaluation form showed the laboratory received an artificial score of 100% on the analytes of albumin and total bilirubin. There was no documentation the laboratory had performed a self-evaluation. 6. Interview with the technical consultant on 4/10/24 at 1:38 PM confirmed an evaluation of the proficiency testing results had not been evaluated for accuracy. 7. Review of the "Proficiency Testing Guidelines" policy, last reviewed May 2022, showed "Survey performance resulting in a score of less than 100% will require further investigation and correction...Any analyte that does not reflect test performance (e.g., when PT does not obtain the agreement required for scoring, or the section receives a zero score for nonparticipation, or late return of results."
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on lack of documentation 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 Troponin I and D-dimer analytes performed on the Alere Triage analyzer every 6 months for two survey cycles conducted on 4/27/22 and 4/10/24. Refer to D5439.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 procedure manual review, lack of documentation, and staff interview, the laboratory failed to ensure the procedure manual contained all the required elements for 3 of 3 procedure manuals reviewed (Alere Triage Troponin I, Alere Triage D-dimer, Beckman Coulter UniCel DxH 600 hematology). The findings were: 1. Interview with testing personnel (TP) #1 on 4/10/24 at 12:34 PM revealed she had worked in the laboratory for 12 years and the procedure manuals had not been updated in that timeframe. TP #1 had a personal notebook she used to document information she needed to remember. The laboratory hired TP #2 on 1/15/24. 2. Interview with the technical consultant (TC) on 4/10/24 at 1:41 PM revealed the laboratory used the manufacturer's instructions for use as their procedure manual. The TC was unable to locate any additional procedures which included the required elements.
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 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 Troponin I and D-dimer analytes performed on the Alere Triage analyzer for 2 of 2 years reviewed (2022, 2023). The laboratory performed approximately 148 Troponin I and 305 D-dimer patient tests per year. The findings were: 1. Review of the laboratory's records showed a calibration verification study was performed for the Troponin I and D-dimer analytes on 4/21/22. The following concerns were identified: a. A calibration verification study was performed on 8/11/22; however, there was no evidence the results were evaluated. b. A calibration verification study was performed on 10/15/22; however, there was no evidence the results were evaluated. c. A calibration verification study was performed on 10/13/23; however, there was no evidence the results were evaluated. 2. Interview with the technical consultant on 4/10

	/24 at 11:43 AM confirmed the calibration verification studies had not been completed as required. THIS IS A REPEAT DEFICIENCY, last cited on 4/27/22.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation, policy and procedure review, and staff interview, the laboratory failed to verify the statistical parameters of quality control material prior to use for 2 or 2 test systems (chemistry, hematology) reviewed. The laboratory performed approximately 131,447 chemistry tests and 67,746 hematology tests per year. The findings were: 1. There was no documentation the laboratory had verified new lot numbers of quality control material prior to being used on the Beckman Coulter DxH 600 hematology analyzer, the Roche Integra 400+ analyzer used for routine chemistry, or the Roche E-411 analyzer used for endocrinology. 2. Interview with the technical consultant on 4/10/24 at 12:29 PM confirmed the statistical parameters of the quality control materials had not been verified before use. 3. Review of the 3/31/16 "Lander Medical Clinic Control procedures" policy showed "...When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available"