Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0519922	05/14/2026
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
D0000	The following deficiencies were a result of an onsite recertification survey conducted from 5/13/26 through 5/14/26. The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D5200 493.1230 Condition: General laboratory systems D6000 493.1403 Condition: Laboratories performing moderate complexity testing; Laboratory Director. .
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on review of the Centers for Medicare and Medicaid 209 Laboratory Personnel Report, review of personnel records, staff interview, review of policy and procedures, lack of documentation, review of quality assessment documentation and proficiency testing records, the laboratory failed to ensure the technical consultant's competency assessment was completed as required (Refer to D5209); failed to review and evaluate proficiency testing results less than 100% (Refer to D5211); and failed to review proficiency test results which received an artificial score of 100% (Refer to D5215) for two survey cycles conducted on 4/10/24 and 5/14/26. In addition, the laboratory failed to have an effective ongoing quality assessment program (Refer to D5291) from January 2025 through April 2026. .
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, staff interview, and review of policy and procedures, the laboratory failed to ensure the technical consultant's competency assessment had been completed for 1 of 2 years reviewed (2025). 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 evidence a competency assessment had been completed in 2025. 3. Interview with the laboratory manager on 5/13/26 at 1:40 PM confirmed no further documentation was available. The technical consultant and laboratory director were unavailable for an interview. 4. Review of the "Personnel Competency Policy April 2024", signed by the laboratory director on 5/7/24, showed "Technical Consultant...Performance evaluation (evaluated at 90 days and then every 6 months for 2 years for new hires, yearly there after)." THIS IS A REPEAT DEFICIENCY, last cited on 4/10/24. .
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 less than 100% for 1 of 20 proficiency testing events reviewed between April 2024 and April 2026. The findings were: 1. Review of the American Proficiency Institute (API) 2025 Hematology event #2 records showed the laboratory scored an 80% on the eosinophil count. There was no documentation the laboratory had evaluated the proficiency testing results. 2. Interview with the laboratory manager on 5/13/26 at 1:13 PM revealed she was unaware of the requirement and was taking over the duties of the technical consultant while he was on leave. 3. Review of the "Proficiency Testing Guidelines" policy 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." THIS IS A REPEAT DEFICIENCY, last cited 4/10/24. .
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 which received an artificial score of 100% due to lack of peer group consensus for 9 of 20 American Proficiency Institute (API) proficiency testing events reviewed from April 2024 through April 2026. The findings were: 1. Review of the 2024 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 2025 API Chemistry Core event #1 proficiency testing comparative evaluation form showed the laboratory received an artificial score of 100% on the analyte of troponin I. There was no documentation the laboratory had performed a self-evaluation. 3. Review of the 2025 API Chemistry Core event #2 proficiency testing comparative evaluation form showed the laboratory received an artificial score of 100% on the analyte of d-dimer. There was no documentation the laboratory had performed a self-evaluation. 4. Review of the 2025 API Chemistry Core event #3 proficiency testing comparative evaluation form showed the laboratory received an artificial score of 100% on the analyte of direct bilirubin. There was no documentation the laboratory had performed a self-evaluation. 5. Review of the 2025 API Hematology event #1 proficiency testing comparative evaluation form showed the educational challenge had not been reviewed. 6. Review of the 2025 API Hematology event #2 proficiency testing comparative evaluation form showed the educational challenge had not been reviewed. 7. Review of the 2025 API Hematology event #3 proficiency testing comparative evaluation form showed the blood cell identification challenge received an artificial score of 100%. There was no documentation the laboratory had performed a self-evaluation. In addition, the educational challenge had not been reviewed. 8. Review of the 2026 API Chemistry core event #1 proficiency testing comparative evaluation form showed the laboratory received an artificial score on the analyte of total bilirubin. There was no documentation the laboratory had performed a self-evaluation. 9. Review of the 2026 API Hematology event #1 proficiency testing comparative evaluation form showed the educational challenge had not been reviewed. 10. Interview with the laboratory manager on 5/14/26 at 1:33 PM confirmed no further documentation was available. 11. Review of the "Proficiency Testing Guidelines" policy 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." THIS IS A REPEAT DEFICIENCY, last cited 4/10/24. .
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by:

	. Based on review of laboratory documentation and staff interview, the laboratory failed to have an effective ongoing quality assessment review of the laboratory's technical and non-technical functions from January 2025 through April 2026. The findings were: 1. Review of the laboratory's documentation showed the technical consultant performed a monthly review of the laboratory's performance which was signed and dated by the laboratory director. The Quality Assurance Assessment included a review to ensure the laboratory's policies were followed in the areas of safety, personnel, proficiency testing, post-analytical assessments, quality control, system and procedure changes, and monitoring. 2. Review of the Quality Assurance Assessment worksheets from January 2025 through April 2026 showed all of the questions to the established questions were marked "Yes"; however, the laboratory had repeat deficiencies in the areas of personnel competency and evaluation of proficiency testing events. 3. Interview with the laboratory manager and clinic manager on 5/14/26 at 11:15 AM confirmed the monthly quality assurance review was not effective. The laboratory director was not available for an interview. .
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . Based on observation, lack of documentation, review of manufacturer's instructions, and staff interview, the laboratory failed to monitor room temperature and humidity in the testing area for 2 of 2 years reviewed (2024, 2025). The laboratory performed approximately 53,400 hematology tests and 700 microbiology tests per year. The findings were: 1. Observation of the laboratory on 5/13/26 at 8:30 AM showed a Sysmex XN 530 analyzer was used for hematology and a Cepheid GeneXpert Xpress analyzer was used for microbiology. Review of the laboratory's documentation showed no evidence the temperature and humidity of the testing area was monitored. 2. Review of the Cepheid GeneXpert Xpress manufacturer's instructions showed the environmental conditions for testing must be between 15 and 30 degrees Celsius and the humidity level should be maintained between 20% and 80%. 3. Review of the Syxmex XN 530 manufacturer's instructions showed the environmental conditions for testing must be between 60- and 95-degrees Fahrenheit and the humidity level should be maintained between 20% and 85%. 4. Interview with the laboratory manager on 5 /14/26 at 10:15 AM revealed environmental monitoring of the testing area was not completed. .
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including

	background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on observation, review of the laboratory's documentation, and staff interview, the laboratory failed to perform function checks on each piece of equipment /instrument it used to ensure accurate and reliable test reporting for 2 of 2 years (2024, 2025) reviewed. The findings were: 1. Observation of the laboratory on 5/13/26 at 8: 30 AM showed the laboratory had two countertop centrifuges and multiple timers. 2. Review of the laboratory's documentation showed no evidence a function check protocol had been developed to ensure accurate and reliable test results of the laboratory's equipment. 3. Interview with the laboratory manager on 5/14/26 at 10:15 AM revealed function checks on the equipment had not been performed. .
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: . Based on observation, review of patient test reports, review of quality control (QC) records, lack of documentation, review of the laboratory's individualized quality control plan (IQCP), and staff interview, the laboratory failed to perform two levels of control with each new kit lot number for testing performed on the Cepheid GeneXpert XPress analyzer (Group B Streptococcus, Clostridium difficile, and Chlamydia trachomatis/Neisseria gonorrhoeae). This failure affected 4 patient tests between 9/3 /25 and 5/14/26. The findings were: 1. Observation of the Cepheid GeneXpert Xpress test kits showed the Group B Streptococcus kit was opened on 9/3/25, the Clostridium difficile kit was opened on 5/11/26, and the Chlamydia trachomatis/Neisseria gonorrhoeae kit was opened on 5/11/26. 2. Review of the laboratory's documentation showed no evidence a positive and negative control was performed prior to patient testing. Review of patient test reports showed a Group B Streptococcus patient test was performed on 3/19/26; a Clostridium difficile patient test was performed on 5/12 /26, and Chlamydia trachomatis/Neisseria gonorrhoeae patient testing occurred on 5 /12/26 and 5/13/26. 3. Review of the laboratory's IQCP for testing on the Cepheid GeneXpert Xpress analyzer, last reviewed by the laboratory director on 9/25/25, showed QC testing was to be completed with each new lot of test cartridges received, major maintenance performed, software upgrades, or at any point the operator suspects instrument malfunction. 4. Interview with the laboratory manager on 5/14/26 at 10:35 AM revealed she was unable to locate documentation quality control had been performed on the testing kits prior to patient use. .

D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on review of proficiency testing records, lack of documentation, review of quality assessment documentation, staff interview, and policy and procedure review, the laboratory director failed to ensure proficiency testing reports were reviewed by the appropriate staff to identify any problems that required corrective action (Refer to D6018) and failed to ensure an effective quality assessment program was established and maintained (Refer to D6020). .
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: . Based on review of proficiency testing records, lack of documentation, and policy and procedure review, the laboratory director failed to ensure proficiency testing reports were reviewed by the appropriate staff to identify any problems that required corrective action. Refer to D5211 and D5215. .
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: . Based on review of laboratory quality assessment documentation and staff interview, the laboratory director failed to ensure an effective quality assessment program was established and maintained from April 2024 through April 2026. Refer to D5291. .