Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0519922	04/27/2022
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: . Based on review of the new test verification documentation for the Cepheid Gene Xpert respiratory panel which included RSV (respiratory syncytial virus), influenza A and influenza B, review of the laboratory's annual workload worksheet, lack of documentation, and staff interview, the laboratory failed to enroll in an approved proficiency testing program for the regulated virology test system for 1 of 2 years of patient testing (2021). The laboratory performed approximately 1,077 respiratory panels in 2021. The findings were: 1. Review of the laboratory's annual workload worksheet showed 1,077 respiratory panels had been performed from 1/1/21 to 12/31 /21. Review of the laboratory's documentation showed no evidence the laboratory was enrolled in proficiency testing. 2. Interview with the laboratory manager on 4/27/22 at 1:27 PM confirmed the laboratory had not enrolled in a proficiency testing program for the virology panel. .
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable

	requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of the laboratory's "Billing Summary Report", review of reporting documentation, and staff interview, the laboratory failed to report 904 SARS-CoV-2 negative test results from 11/27/20 through 4/27/22. The findings were: 1. Observation of the laboratory on 4/27/22 at 12:30 PM showed testing for SARS-CoV-2 was performed using a molecular platform on the Cepheid Gene Xpert. 2. Review of the "Billing Summary Report" from 11/27/20 through 4/27/22 showed the laboratory had performed 1,304 SARS-CoV-2 tests. 3. Interview and review of the reporting documentation with the laboratory manager on 4/27/22 at 4 PM revealed the laboratory had reported 400 positive SARS-Co-V-2 to the State Public Health Laboratory, however the laboratory had not reported 904 negative test results. Further the laboratory manager stated he was not aware of the regulation until recently, and confirmed the negative test results had not been reported to the State Public Health Laboratory.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on review of the new test verification documentation for the Cepheid Gene Xpert respiratory panel which included SARS-CoV-2, review of the laboratory's annual workload worksheet, lack of documentation, and staff interview, the laboratory failed to at least twice annually verify the accuracy of the SARS-CoV-2 test for 1 of 2 years of patient testing (2021). The laboratory performed approximately 1,500 SARS-CoV-2 tests in 2021. The findings were: 1. Review of the laboratory's annual workload worksheet showed approximately 1,500 SARS-Co-V-2 tests had been performed from 1/1/21 to 12/31/21. Review of the laboratory's documentation showed no evidence the laboratory had verified the accuracy of the test. 2. Interview with the laboratory manager on 4/27/22 at 1:27 PM confirmed the laboratory had not verified the accuracy of the SARS-CoV-2 test in 2021. .
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: . Based on lack of documentation and staff interview, the laboratory failed to have a written procedure for reporting SARS-CoV-2 positive and negative test results. The findings were: 1. Review of the laboratory's procedure manuals showed no evidence a policy and procedure had been developed in regard to reporting SARS-CoV-2 positive and negative test results to the appropriate agencies. 2. Interview with the laboratory manager on 4/27/22 at 4 PM confirmed the laboratory did not have a written procedure for reporting SARS-CoV-2 test results. .
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 free thyroxine, ferritin, testosterone, prostate specific antigen, thyroid stimulating hormone, and human chorionic gonadotropin hormone analyzed on the Roche Cobas e411 instrument for 2 of 2 years reviewed (2020, 2021). The laboratory performed approximately 1,670 immunoassay tests per year. The findings were: 1. Review of the laboratory's records showed a calibration verification had been performed on 1/24/20, 4/7/21, and 3/7/22. 2. Interview with the laboratory manager on 4/27/22 at 2:38 PM confirmed the calibration verification had not been performed every 6 months as required. .
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following

	for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on review of the quality control (QC) records, review of the laboratory's individualized quality control plan (IQCP), lack of documentation, review of the "Billing Summary Report", staff interview, and review of the manufacturer's instructions, the laboratory failed to perform two levels of quality control each day of patient testing for 46 days of patient testing reviewed (12/22/20 through 2/6/21) for the Cepheid Gene Xpert molecular respiratory panel (SARS-CoV-2, respiratory syncytial virus (RSV), influenza A, and influenza B). The laboratory performed 121 respiratory panels during this timeframe. The findings were: 1. Review of the QC records showed the laboratory performed a positive and a negative control on the Cepheid Gene Xpert analyzer for the respiratory panel on 12/21/20 and again on 2/18 /21. Review of the "Billing Summary Report" showed 121 respiratory panels had been performed between 12/22/20 and 2/6/21. 2. Further review of the QC records showed a positive and negative control was performed on 3/15/21, 1/26/21, 9/26/21, 10/25/21, 12/6/21, 12/22/21, 2/15/22, and 4/11/22. 2. Review of the IQCP, last reviewed 12/6 /19, for the Cepheid Xpert instrument showed the tests of Chlamydia/Neisseria gonorrhoeae (CT/NG), Group B Streptococcus (GBS), and Clostridium difficile (C-diff) were included in the quality control plan. There was no evidence the IQCP had been updated to include the respiratory panel. 3. Interview with the laboratory manager on 4/27/22 at 3:22 PM revealed the laboratory had included the respiratory viruses performed on the Cepheid Xpert in the IQCP which included the tests of CT /NG, GBS, and C-diff. The laboratory manager confirmed the laboratory had not updated the IQCP and had not performed positive and negative control materials each day of testing for the respiratory viruses. 4. Review of the Cepheid Xpert manufacturer's instructions for use showed "The ultimate responsibility for determining the type and frequency of testing controls remains with the laboratory director. Laboratories should follow all applicable federal and local regulations." .
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: . Based on review of the new test verification documentation for the Cepheid Gene Xpert respiratory panel which included RSV (respiratory syncytial virus), influenza A and influenza B, review of the laboratory's annual workload worksheet, lack of documentation, and staff interview, the laboratory director failed to ensure the laboratory was enrolled in an approved proficiency testing program for the regulated virology test system for 1 of 2 years of patient testing (2021). The laboratory performed approximately 1,077 respiratory panels in 2021. Refer to D2000.