Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0519922	04/05/2018
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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Individualized Quality Control Plan (IQCP) review and interview with staff, the laboratory failed to perform a risk assessment for 4 of 4 tests reviewed, (Group B Strep. Nisseria gonorrhea, Chlamydia trachomatis, and Clostridium difficile) testing performed on the Cepheid Gene X pert test system. The laboratory performed approximately 10 to 15 tests per week. Findings include: 1. The IQCP failed to include a risk assessment for each test performed using the Cepheid Gene X pert test system. The laboratory failed to include the sources of error and mitigating processes the laboratory performed to ensure the risk of testing errors was minimal for reducing the frequency of quality control performance to each new lot number of test kits for Group B Strep, Chlamydia, Nisseria gonorrhea, and C. difficile testing. 2. In an interview conducted on 04/05/2018 at approximately 12:30 P.M., staff confirmed the IQCP did not include a risk assessment for determination the reduced frequency for quality control performance would not be likely to miss testing errors that quality control would detect for Gene Xpert testing.
D5787	TEST RECORDS CFR(s): 493.1283(a)

	The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on patient test reports review and interview with staff, the laboratory record system failed to include the identity of the personnel who performed 13 of 34 test reports reviewed. Findings include: 1. Patient test reports review included the initials of the personnel who performed the tests or an "[A]". 2. Test reports review included documentation of the [A] for specimens numbers: 6428, 12309, 12422, 31368, 13121, 3556, 10721, 27790, 4123, 9313, 34372, 2272, and 1062 3. In an interview conducted on 04/05/2018 at approximately 11:30 A.M. staff stated the tests reported with [A] were auto approved by the laboratory information system and did not have a person associated with the results. Staff stated the laboratory did not have a mechanism to record the person responsible for test performance and reporting for each of tests reported that were auto approved.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on patient test report review, test reagent package review, and interview with staff, the laboratory failed to monitor routine chemistry test reports to identify errors in test reports for 2 of 2 Phosphorus test reports reported as phosphate. Findings include: 1. Patient test reports for patient's specimens #10721 and #12422 included the Analyte phosphate on the test report. The laboratory actually tested and reported phosphorus. 2. The test system reagent package label review was worded as Phosphorus. 3. In an interview, on 04/05/2018 at approximately 3:00 P.M., staff confirmed the test Analyte was incorrect on the test report and that post analytic test review did not identify the problem.