Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0519922	09/10/2020
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
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on procedure manuals review, lack of documentation, and interview with staff, the laboratory failed to include in the manufacturer's operator's manuals the laboratory specific procedures for 4 of 4 test systems reviewed. The laboratory performed approximately 130,000 tests per year using the 4 test systems. Findings include: 1. Procedure manuals reviewed for Roche Cobas Integra 400 and E411 analyzers, Beckman Coulter DxH cell counter, and Cepheid molecular test system for microbiology and virology testing failed to include laboratory specific instructions for documentation of corrective actions taken for: out of range quality control results; how to document reporting of critical values, how to enter results into the patient's test record, and steps to take when the system becomes inoperable. 2. In an interview conducted on 09/10/2020 at approximately 3:30 P.M., the laboratory manager confirmed the procedure manuals did not include the laboratory specific information.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(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 personnel records review, lack of documentation, and interview with staff, the new director failed to sign and date as approved laboratory procedure manuals for Bacteriology, Virology, Routine Chemistry, Endocrinology, and Hematology tests. Findings include: 1. Personnel records review included documentation the laboratory director changed in May of 2019. 2. Procedure manual review failed to include the signature and date of approval for laboratory procedure manuals by the new director. 3. In an interview conducted on 09/10/2020 at approximately 3:00 P.M., the laboratory manager confirmed the new director had not signed and dated the laboratory procedure manuals for the Cobas Integra 400, the Roche E411, Beckman Coulter DxH cell counter, and Cepheid virology, microbiology and microscopic urinalysis test procedures.