Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0926382	07/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Teton Womens Health Center	2001 S Woodruff Ave #10, Idaho Falls, ID	

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 a record review and an interview with the laboratory lead, the laboratory failed to perform quality control for each new lot of test kits received prior to patient testing and failed to establish an Individualized Quality Control Plan (IQCP) for the test BD Affirm VPIII microbial identification system since the last survey on September 20, 2017. Findings: 1. A review of quality control results from the BD Affirm microbial test kit revealed the laboratory failed to perform quality control on each new kit lot number received between August 18, 2018 and June 6, 2019 prior to reporting patient test results for Candida albicans, Trichomonas vaginalis, and Gardnerella vaginalis. 2. A review of the laboratory procedures revealed the laboratory failed to establish an IQCP that includes the number, type, and frequency of quality control used for each test system as specified by the manufacturers. 3. The laboratory performed approximately 105 microbial tests between August 18, 2018 and June 6, 2019. 4. An interview with the laboratory lead on July 15, 2019, at 1:20 PM, confirmed the laboratory failed to establish an IQCP and perform quality control for each new kit lot received.
D5781	CORRECTIVE ACTIONS

	CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to identify and document corrective actions for refrigerator temperatures out of range where BD Affirm VPIII microbial test kit was stored repeatedly since August 2018. Findings: 1. A record review of the laboratory refrigerator temperature chart revealed the acceptable reference range was 2 to 8C. 2. a review of the refrigerator temperature chart revealed the laboratory staff failed to identify and document corrective actions for the refrigerator temperatures that were below the range, documented at 0C, for 14 out of 14 days in November 2018, 10 out of 10 days in December 2018, 9 out of 9 days in February 2019, 18 out of 18 days in March 2019, 9 out of 9 days in April 2019. 3. An interview with the laboratory lead on July 15, 2019, at 1:45 PM, confirmed the laboratory staff failed to document and correct the low temperatures for the refrigerator.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a procedure review and an interview with the laboratory lead, the laboratory director failed to ensure a quality assessment program for the BD Affirm VPIII microbial test was established and maintained to identify and correct problems during all phases of testing since the last the survey on September 20, 2017. Findings: 1. A record review revealed the laboratory director failed to establish a policy or procedure for a system to monitor, assess, and correct problems in the preanalytic, general laboratory system, analytic, and post-analytic processes in the laboratory. 2. The laboratory performed approximately 300 microbial tests in 2018. 3. An interview with the laboratory lead on July 15, 2019, at 2:05 PM, confirmed the laboratory director failed to establish and write a quality assessment policy or procedure for the BD Affirm VPIII test system.