Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0926382	(X3) Date Survey Completed 06/14/2023
Name of Provider or Supplier Teton Womens Health Center	**Street Address, City, State** 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
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 a review of laboratory policies and procedures and an interview with the laboratory lead on 6/14/2023, the laboratory failed to establish a policy for training and competency. The findings include: 1. A review of laboratory policies and procedures identified that the laboratory failed to establish a policy listing requirements for train new testing personnel, steps for monitoring testing personnel competency that include the six required elements and identify when remedial training is needed. 2. An interview with the laboratory lead on 6/14/2023 at 9:55 am confirmed the above finding. 3. The laboratory reports performing 450 tests annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observations and an interview with the laboratory lead on 6/14/2023, the laboratory failed to discontinue the use of reagents when they had exceeded their expiration date. The findings include: 1. Direct observation in patient exam room five identified one bottle of Consult Diagnostics 10 SG urine reagent strips lot

	URS0120162 expiration 4/2/2023 and a direct observation in the laboratory identified one bottle of Consult Diagnostics 10 SG urine reagent strips lot URS0120162 expiration 4/2/2023 that the laboratory failed to discontinue use of before they exceeded the expiration. 2. An interview with the laboratory lead on 6/14/2023 at 10: 19 am confirmed the above expired reagents. 3. The laboratory reports performing 4800 urinalysis tests annually.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of patient laboratory reports and an interview with the laboratory lead on 6/14/2023, the laboratory failed to list all testing performed and their results for BD Affirm testing on patient laboratory test reports. The findings include: 1. A review of patient laboratory test reports for BD Affirm panel testing identified that the laboratory failed to list all test analytes performed and their corresponding results. 2. An interview with the laboratory lead on 6/14/2023 at 10:00 am confirmed that the above findings. 3. The laboratory reports performing 450 BD Affirm tests annually.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of patient laboratory test reports and an interview with the laboratory lead on 6/14/2023, the laboratory failed to include the normal values for the reported BD Affirm analytes on patient laboratory test reports. The findings include: 1. A review of patient laboratory test reports identified that the laboratory failed to include the normal values for the analytes tested in the BD Affirm panel: Candida species, Gardnerella vaginalis, Trichomonas vaginalis. 2. An interview with the laboratory lead on 6/14/23 at 10:00 am confirmed the above findings. 3. The laboratory reports performing 450 BD Affirm tests annually.