Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520979	08/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Teton Valley Hospital	120 E Howard St, Driggs, 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 training documentation, competency assessments, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and an interview with the laboratory manager on 8/10/2021, the laboratory failed to establish and follow written policies and procedures to assess testing personnel in accordance with 42 C.F. R. 493.1451(b)(7)(8). The findings include: 1. A review of training and competency records identified that five (5) of eight (8) testing personnel listed on the CMS 209 failed to have documentation of six (6) month competency which included the six parameters as listed in 493.1451(b)(7)(8). 2. A review of training and competency records identified eight (8) of eight (8) testing personnel listed on the CMS 209 failed to have documentation of annual competency which included the six parameters as listed in 493.1451(b)(7)(8) for 2020. 3. An interview with the laboratory manager on 8 /10/2021 at 8:25 am confirmed the above findings.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

	This STANDARD is not met as evidenced by: Based on review proficiency testing (PT) records and an interview with the laboratory manager on 8/10/2021, the laboratory failed to evaluate the accuracy of any analyte, specialty or subspecialty that was assigned an artificial score of 100% because it was ungraded by the PT provider. The findings include: 1. A review of Immunology /Immunohematology 2020 event 1 records from American Proficiency Institute (API) identified a C-Reactive Protein sample (CRP-01) that was given an artificial score of 100% that the laboratory failed to evaluate for accuracy. 2. A review of Immunology /Immunohematology 2020 event 2 records from API identified a C-Reactive Protein sample (CRP-03) that was given an artificial score of 100% that the laboratory failed to evaluate for accuracy. 3. A review of Hematology/Coagulation 2020 event 3 records from API identified one urine sediment sample (US-06) was ungraded due to lack of consensus resulting in an artificial score of 100% that the laboratory failed to evaluate for accuracy. 4. A review of Chemistry 2020 event 1 records from API identified a Vitamin B-12 sample (IA-02) that was given an artificial score of 100% that the laboratory failed to evaluate for accuracy. 5. A review of Chemistry 2020 event 2 records from API identified a Vitamin B-12 sample (IA-06) and a 25-OH Vitamin D sample (IAS-06) that were given an artificial score of 100% that the laboratory failed to evaluate for accuracy. 6. A review of Routine Microbiology Combination 2020 event 1 records from College of American Pathologists (CAP) identified that one urine culture bacterial identification sample (UC-03) was ungraded due to lack of consensus resulting in an artificial score of 100% that the laboratory failed to evaluate for accuracy. 7. An interview with the laboratory manager on 8/10 /2021 at 9:30 am confirmed that the laboratory did not evaluate the accuracy of ungraded PT results that were given an artificial score of 100%. 8. The laboratory reports performing 123,320 moderate and high complexity tests annually.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a random record review of Quality Control (QC) documentation and an interview with the laboratory manager on 8/10/2021, the laboratory failed to successfully perform two levels of QC daily for each quantitative procedure. The findings include: 1. A random record review of QC from the Ortho Vitros 5600 identified that the laboratory did not have a result on 4/9/2021 for level 3 Biorad QC lot number 45793 for the following analytes: glucose, total protein, uric acid, albumin, triglyceride,cholesterol, amylase, chloride, potassium, sodium, carbon dioxide, phosphorus, creatinine, urea, calcium, magnesium, alkaline phosphatase, alanine aminotransferease, aspartate aminotransferase, creatine kinase. 2. An interview with the laboratory manager on 8/10/2021 at 10:48 am confirmed that there were not two levels of QC on 4/9/2021 for the above analytes. 3. The laboratory performed chemistry testing for nine (9) patients on 4/9/2021.
D5451	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a random review of immunohematology quality control (QC) records, patient records and an interview with the laboratory manager on 8/10/2021, the laboratory failed to document control material results with graded or titered reactivity and include negative control material. The findings include: 1. A random record review of immunohematology QC and immunohematology patient logs for 2019, 2020 and 2021 identified that the laboratory failed to document QC with a graded or titered reactivity and a negative control on 11/9/2019, 4/27/2020, 4/28/2020, 2/16 /2021, 3/16/2021, 5/14/2021 and 5/18/2021 as required by regulation for all immunohematology testing. 2. One (1) patient blood and Rh type was performed on 11 /9/2019 and the laboratory failed to document positive QC (1-4+) and negative QC. 3. One (1) patient blood, Rh type and antibody screen was performed on 4/27/2020 and the laboratory failed to document positive QC (1-4+) and negative QC. A Crossmatch of two (2) units was performed for this patient on 4/28/2020 and the laboratory failed to document positive QC (1-4+) and negative QC. 4. One (1) patient blood and Rh type, antibody screen and a crossmatch of two (2) units was performed on 2/16/2021 and the laboratory failed to document positive QC (1-4+) and negative QC. 5. One (1) patient blood and Rh type, antibody screen and a crossmatch of two (2) units was performed on 3/16/2021 and the laboratory failed to document positive QC (1-4+) and negative QC. 6. One (1) patient antibody screen was performed on 5/14/2021 and the laboratory failed to document positive QC (1-4+) and negative QC. 7. Four (4) units had blood and Rh type performed as unit checks on 5/18/2021 and the laboratory failed to document positive QC (1-4+) and negative QC. 8. An interview with the laboratory manager on 8/10/2021 at 4:10 pm confirmed the above findings. 9. The laboratory reports performing 430 immunohematology tests annually.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on a review of the "Gram Stain Control Result Log" and an interview with the laboratory manager on 8/11/2021, the laboratory failed to check the reactivity of the gram stain reagents using control organisms weekly. The findings include: 1. A review of the "Gram Stain Control Result Log" identified that the laboratory failed to perform gram stain controls weekly for the month of April 2021 using a gram positive and gram negative organism. 2. An interview with the laboratory manager on 8/11 /2021 at 8:20 am confirmed that the laboratory failed to QC the gram stain reagents weekly. 3. The laboratory reports performing 150 gram stains annually.