Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521180	06/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Clearwater Valley Hospital	301 Cedar St, Orofino, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of the Sure-Vue rapid plasma reagin (RPR) package insert, patient test results and quality control (QC) logs and an interview with testing personnel 1 (TP1) on 6/24/2021, the laboratory failed to follow the manufacturer's instructions for Syphilis Serology testing. The findings include: 1. A review of the Sure-Vue RPR package insert, patient test results and QC log identified that the laboratory failed to perform and document and accuracy check on the antigen dispensing needle to ensure that the correct volume of antigen was used as required by the manufacturer. 2. A review of the Sure-Vue RPR package insert, patient test results and QC log identified that the laboratory failed to verify that the rotator speed used for testing met the manufacturers requirements. 3. An interview with TP1 on 6/24/2021 at 1:06 pm confirmed the above findings 4. The laboratory reports performing 193 RPR tests annually.
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 record review of immunohematology quality control (QC), patient testing logs and an interview with testing personnel 2 (TP2) on 6/24/2021, 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 testing 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 6/18/2019, 6/25/2019, 7/9/2019, 7 /10/2019 and 7/13/2019. 2. One patient blood and Rh type, antibody screen and crossmatch were performed on 6/18/2019, two were performed on 7/9/2019 and the laboratory failed to document positive QC (1-4+) and negative QC for these days as required by regulation for all immunohematology testing. 3. One patient blood and Rh type was performed on 6/18/2019, one was performed on 7/10/2019 and two were performed on 7/13/2019 and the laboratory failed to document positive QC (1-4+) and negative QC for these days as required by regulation for all immunohematology testing. 4. An interview with TP2 on 6/24/2021 at 2:50 pm confirmed the above findings. 5. The laboratory reports performing 767 immunohematology tests annually.