Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0656919	06/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Wallowa Memorial Hospital Lab	601 Medical Parkway, Enterprise, OR	

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 review of the syphilis serology quality control and patient logs, and interview with the technical supervisor (TS), the laboratory failed to ensure that the needle use to deliver the syphilis antigen suspension was dispensing the correct volume: Findings include: 1. Review of the syphilis serology quality control and patient logs revealed there was no indication that the needle dispense accuracy check was performed. The procedural notes indicated that " the needle should deliver 60 drops plus or minus 2 of antigen suspension per milliliter when held in a vertical position. To perform accuracy check on the needle, attached the needle to a 1 or 3 ml syringe. Fill the syringe with antigen suspension and, holding the syringe in a vertical position count the number of drops delivered in 0.5 ml. The needle is considered satisfactory if 30 +/= 1 drops are obtained. The needle dispenses a 17 ul drop of antigen." 2. The laboratory uses the the Sure-Vue Rapid Plasma Reagin (RPR) test kit and performs 150 to 200 RPR per year. 3. Interview with the TS on 06/21/2023 at 3: 00 PM confirmed the laboratory failed to perform needle dispense accuracy check.
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 review of the approved normal values in the laboratory procedure manual, two of two patients reports, and interview with the technical supervisor (TS), the laboratory failed to ensure the test report included pertinent normal ranges as determined by the laboratory. Two of 17 chemistry normal values listed on the laboratory information system (LIS) report differed from those in the approve procedure manual. Findings include: 1. Review of the patient report from the LIS system revealed Aspartate aminotransferase (AST) and Alanine transaminase (ALT) did not correctly match those reference ranges in the procedure manual. LIS patient report Procedure manual. AST 15-37 U/L 16-38 U/L ALT 30-65 U/L 18-63 U/L 2. Interview with the TS on 06/21/2023 at 2:00PM confirmed the laboratory failed to ensure correct reference ranges approved in the procedure manual were included on the LIS patient reports.