Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0696792	01/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Valley Women's Health	295 S 1470 E Suite 200, St George, UT	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on proficiency testing records review, lack of documentation, and interview with staff, the laboratory director failed to attest proficiency specimens were tested in the same manner as patient specimens for 5 of 6 Wisconsin State Laboratory of Hygiene (WSLH)proficiency testing events reviewed. Findings include: 1. Proficiency testing attestation statements reviewed failed to include the signature of the laboratory director for WSLH events 1 and 3 of 2017 and events 1, 2, and 3 of 2018. 2. In an interview on 01/09/2019, the laboratory manager confirmed the laboratory director had not signed the attestation statements and that the laboratory did not have a director's delegation of duty authorization to a qualified technical consultant.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems

	activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on quality control records review, lack of documentation, and interview with staff, the laboratory failed to document and retain the lot numbers and expiration dates for serum pregnancy tests in use from January 2017 to January 2019. Findings include: 1. Quality control records review failed to include the serum pregnancy test kit's lot numbers, expiration dates, and the dates the reagents were placed in use by the laboratory. 2. In an interview with the laboratory manager on 01/09/2019 at approximately 5:10 P.M., the laboratory manager stated the lab did not retain the serum pregnancy test kit lot numbers and the kit expiration dates.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(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--Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observation and confirmation by the laboratory manager, the laboratory failed to use control materials of the same matrix as patient samples for serum human chorionic gonadotrophin (pregnancy) testing. The time period the laboratory used control materials of a different matrix was not determined. The laboratory tested approximately one serum pregnancy test per day. Findings include: 1. Direct observation of the laboratory test refrigerated storage space failed to include pregnancy controls that were made from the same serum matrix. The pregnancy controls were made from urine. 2. The laboratory manager confirmed, in an interview conducted on 01/09/2019 at approximately 5:00 P.M., the controls were not of the same matrix as patient serum pregnancy specimens.