Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0701320	06/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Valley Obstetrics & Gynecology, Provo	585 North 500 West, Provo, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on laboratory test record review, the regulated analyte list in 42 CFR subpart I, lack of documentation, and interview with the director, the laboratory failed to enroll in proficiency testing (PT) for regulated analyte testing in 7 of 7 specialties /subspecialties (Syphilis Serology, General Immunology, Routine Chemistry, Endocrinology, Hematology, ABO Group & Rh Type, and Antibody Detection (nontranfusion). Finding include: 1. Laboratory test records document testing for: Syphilis using the Rapid Plasma Reagin Method; ABO, Rh, and Antibody Detection using the Ortho Vision; 17 regulated Routine Chemistry analytes tested on the Ortho Virtros 350; 6 regulated analytes tested in the subspecialties of Immunology and Endocrinology on the Ortho ECi, and Complete Blood Counts performed on the Sysmex 430. 2. The laboratory lacked documentation of enrollment with an approved PT program. 3. The laboratory director confirmed on 06/24/2019 at approximately 10: 00 am the laboratory had failed to enroll in PT.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d)

	Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on procedure manual record review and interview with the director, the laboratory director failed to date and sign as approved, the manufacturer's operator instructions for 6 of 6 test systems in use (Sysmex 430, Cepheid Gene Xpert, Ortho Vision, Ortho Virtros 350, Ortho ECi, and manual Rapid Plasma Reagin {RPR}). Finding include, 1. The laboratory used the manufacturer's instructions and/or package inserts as test reference material, as well as a written sample handling procedure and instructions on using the laboratory information system, as their standard operating procedures (SOPs). 2. The procedures lacked documentation of the laboratory director's approval. 3. The laboratory Director stated during the survey she had failed to sign and date as approved the procedures in use or write laboratory specific SOPs.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on laboratory test method verification record review, lack of documentation, and interview with the director, the laboratory failed to verify it could obtain all performance specifications comparable to the manufacturer for testing performed on 4 of 6 test systems used for patient testing (Cepheid Gene Xpert, Ortho Vision, Ortho ECi, and Rapid Plasma Reagin {RPR}). 1. The laboratory lacked documentation of verification studies for accuracy and precision for Group B Streptococcus, Chlamydia Trachomatis, and Neisseria Gonorrhea testing on the Cepheid Gene Xpert. 2. The laboratory lacked documentation of precision testing for ABO Blood Group, Rh, and Antibody Detection on the Ortho Vision. 3. The laboratory lacked documentation of test accuracy verification for Rubella testing on the Ortho ECi. 4. The laboratory lacked documentation of verification studies for accuracy and precision for Syphilis testing performed using the RPR method. 5. The laboratory director confirmed during the survey on 06/24/2019 the laboratory had not performed verification studies for RPR, did not verify precision on the Ortho Vision, and could not locate verification studies done on the Cepheid Gene Xpert and accuracy testing records for Rubella testing.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within

	the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on manufacturer instructions review, lack of documentation, and interview with staff, the laboratory failed to follow the manufacturer's (Arlington Scientific) instructions to check the diameter of the automatic rotator for their Rapid Plasma Reagin (RPR) test for Syphilis to ensure a 3/4 inch rotation. The laboratory began RPR testing in 01/2019 and performs approximately 800 immunology tests a month. Findings include: 1. The RPR manufacturer instructions state to check the needle delivery and the rotator RPMs and circumference. 2. The laboratory lacked documentation they checked the rotator circumference. 3. The laboratory director confirmed on 06/24/2019 during the survey, the laboratory had not checked the rotator circumference.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on patient test record review, quality control (QC) record review, lack of documentation, and interview with the director, the laboratory failed to perform a negative and positive control each day of testing for 3 of 3 Bacteriology tests performed on the Cepheid Gene Xpert (Group B Streptococcus {GBS}, Chlamydia Trachomatis {CT}, and Neisseria Gonorrhea {GC}) for 2 of 2 days of testing reviewed. The laboratory began Bacteriology testing in 01/2019 and performs approximately 1000 tests a month. Finding include: 1. Patient tests records document GBS testing performed on 03/29/2019 for patient 190880090, and CT and GC testing on 04/29/2019 for patient 191190080. 2. The laboratory QC records failed to contain documentation of 2 levels of QC for GBS on 03/29/2019 and 2 levels of QC for CT and GC on 04/29/2019. 3. The laboratory lacked documentation of an Individualized Quality Control Plan (IQCP) demonstrating they could accurately perform testing using a reduced frequency QC protocol. 4. The laboratory director stated on 06/24 /2019 at approximately 3:00 pm they performed Bacteriology QC once a month, but had not developed an IQCP plan.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the director, the laboratory director failed to ensure a quality assessment program was established to ensure the quality of services provided. The laboratory began testing in 01/2019 and performs approximately 180,000 annually in 9 specialties/subspecialties. Finding include: 1. The laboratory lacked documentation of a written quality assessment plan to monitor test performance throughout the preanalytical, analytical, and postanalytical phases of testing. 2. The director confirmed on 06/24/2019, during survey, a quality plan had not been established.