Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0701320	01/26/2021
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
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 temperature records review, test records review, lack of documentation and interview with staff, the laboratory failed to retain incubator, specimen storage, and reagent temperature records for at least two years for records reviewed from January 29, 2019 to January 26, 2020. The laboratory failed to retain Rapid Plasma Reagin (RPR) quality control records for at least 2 years from 01/01/2019 to 07/01/2019. Findings include. 1. The laboratory records review for recording storage refrigerators, freezers and incubators began in 09/2019. 2. Test records review included documentation beginning on 01/14/2019. 3. RPR quality control records review failed to include the quality control performance prior to 07/01/2019. 3. In an interview conducted on 01/26/2021 at approximately 4:55 P.M. the director stated the records were not available prior to September 2019 for temperatures and prior to 07/2019 for RPR quality control records.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of

	accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on quality control record review, patient test records review, and interview with staff the laboratory failed to document corrective actions taken for one of one day of testing when the Creatinine upper level of control failed to be in control 3 of 4 times tested. The laboratory performed approximately 10 to 15 tests per day. Findings include: 1. A. Quality control records review for creatinine tests performed on 01/24 /2020 failed to include documentation of corrective actions taken for control 3 out of range results of 6.9, 7.0, and 7.01. The acceptable range for the control was 0.5 to 1.4 mg/dl. B. Quality control records review for Estradiol failed to include corrective actions taken for Estradiol control accepted for level 1 results of 68.6 (acceptable range was 77.685- 117.50) on 10/28/2019. 2. A. Patient test records review included a record of patient creatinine testing and reporting on 01/24/2020 for patient accession number 2002201971 in the Comprehensive Metabolic Profile. B. Patient test records review included a record of patient Estradiol testing and reporting on 10/28/2019 for patient accession number 193010006 with an Estradiol concentration of 15.83 pg/ul. 3. In an interview conducted on 01/26/2021 the laboratory director confirmed corrective actions were not documented for the out of range quality control results for Creatinine and Estradiol.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; 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 ensure a review of all proficiency testing reports to evaluate he laboratory's performance and to identify any problems that require corrective action for 4 of 4 failed proficiency results reported (Estradiol [E2}, Free Thyroxine [FT4], Thyroid Stimulating Hormone [TSH}, and Vitamin D[Vit D]) on the 2020 3rd event Chemistry Core module. Findings include: 1. A. Proficiency test records review for the 3rd Core Chemistry event of 2020 included a score of 40% for E2. The laboratory reported E2 for failed specimens as: IA -12 as 369 (acceptable range was 267-364 pg/ml) IA-14 as 534 (acceptable range was 416-495) IA-15 as 640 (acceptable range was 510-603) B. The laboratory scored 40% for FT4 reporting FT4 failed specimens as: C11 as 3.5 (acceptable range was 6.5-7.4 ng/dl) C12 as 6.3 (acceptable range was 3.2-6.0) C14 as 4.5 (acceptable range was 5.3-7.3) C. The laboratory scored 20% for TSH reporting TSH failed specimens as: CH-11 as 1.78 (acceptable range was 6.15-8.51 uIU/ml) CH 12 as 5.79 (acceptable range was 2.4-3.9) CH 14 as 2.89 (acceptable range was 4.72-6.54) CH 15 as 7.9 (C11 as 3.5 (acceptable range was 6.5-7.4 ng/dl) CH 12 as 6.3 (acceptable range was 3.2-6.0) CH 14 as 4.5 (acceptable range was 1.44-1.99) D. The laboratory scored 60% for Vit D reporting Vit D failed specimens as: IAS 13 as 27 (acceptable range was 13-26 ng/ml)

	IAS 14 as 104 (acceptable range was 70-96) 2. In an interview conducted on 01/26 /2021 at approximately 4:50 P.M. the director confirmed corrective actions were not completed for the failed tests.
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 laboratory records review, lack of documentation, and interview with the director, the director failed to establish a quality assessment program to evaluate testing quality over the entire testing process including general laboratory, pre-analytic, analytic, and post analytic testing for Diagnostic Immunology, General Immunology, Routine Chemistry, Endocrinology, Hematology and non transfusion Immunohematology testing. Findings include: 1. The laboratory lacked qualify assessment documentation for review of specimen collection, processing, and storage; review of analytic testing processes including corrective actions taken when quality control was out of range, shifts and trends of quality control results, reagent review for out of date reagents or reagents that show performance deterioration, and lack of review of patient test results to ensure the test reports have positive identification of the specimen, the reports include the tests requested within the laboratory stated turn around time, units of measure, normal range and critical values are reported. 2. In an interview conducted on 01/26/2021 at approximately 5:00 P.M. the director stated quality assessment documentation was not maintained from January 2019 to January 2021.