

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1070679	(X3) Date Survey Completed 03/15/2022
Name of Provider or Supplier Valley Urology Inc	Street Address, City, State 6113 N Fresno St Ste 101, Fresno, CA	
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	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control (QC) records for SHBG test and interview with the laboratory technical consultant on March 15, 2022, at 12:34 pm, the laboratory failed to provide any verification or establishment records of acceptability criteria for the QC lot # 189405. The findings include: See D5469.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's quality control (QC) records for SHBG test and interview with the laboratory technical consultant on March 15, 2022, at 12:34 pm, the laboratory failed to provide any documentation showing that it had established or verified the mean and standard deviation of the QC used. The findings include: 1. The laboratory used Beckman Access automated instrument to test SHBG. The instrument input record showed that the laboratory used the mean value for QC1, 9.7 and QC2, 95, respectively. Though, for the same lot # 189405, the QC manufacturer's record showed the mean value of QC1, 9.56 and QC2, 102, respectively. The technical consultant said that the laboratory had established the QC values by running 20 times and input into the instrument. However, the laboratory could not provide any documentation showing that it had established the QC values by running 20 times. Therefore, the accuracy of the used QC acceptability criteria could not be assured and might have been negatively impacted on patient results. 2. The laboratory technical consultant on March 15, 2022, at 12:34 pm, affirmed that the laboratory did not have the establishment record of QC means used. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/21/2022, stated that the laboratory performs approximately 2,263 SHBG tests, annually.

D6020

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 the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's quality control (QC) records for SHBG test and interview with the laboratory technical consultant on March 15, 2022, at 12:34 pm, the laboratory director failed to ensure that the quality control programs are established for the SHBG test. The findings include: See D5469.