

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0553139	(X3) Date Survey Completed 12/21/2020
Name of Provider or Supplier Greater Long Beach Genito Urinary Medical Group	Street Address, City, State 3650 South St Ste 408, Lakewood, 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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing records and interview with the testing personnel (TP) and technical consultant (TC); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the Testosterone analyte. The finding included: 1. Based on review of PT records for Q1-2019 and Q3-2020, AAB reported an unsatisfactory score of 50% for the Testosterone analyte. The laboratory failed to report an acceptable test value for one (1) out of two (2) tested samples: Event Reported Intended range Q1-2019 174 89-165 Q3-2020 939 402-747 2. Based on the laboratory testing declaration submitted at the time of the survey on 12/21/2020 the laboratory analyzed and reported approximately 350 Testosterone tests during the time the laboratory had unsatisfactory proficiency testing results. 3. The TP and TC affirmed 12/21/2020 at approximately 12:00 p.m. that the laboratory received the above unsatisfactory proficiency testing scores.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>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</p>

identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on the review of the American Association of Bioanalysts proficiency testing results, laboratory policies and procedures, records, and interview with the testing personnel; the laboratory director failed to ensure 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. The findings include: See D2087