

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1089622	(X3) Date Survey Completed 10/17/2023
Name of Provider or Supplier Genex Laboratories	Street Address, City, State 1301 N San Fernando Blvd, Burbank, 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
D2076	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) Proficiency Testing (PT) records and interview with the laboratory technical supervisor (TS); it was determined that the laboratory failed to attain a score of least 80 percent of acceptable responses for Antistreptolysin O (ASO) for the third event of 2020 (Q3-2022). The findings included: 1. Based on review of PT records for Q3-2020, API reported an unsatisfactory score of 40% for RA/RF analyte as follow: Sample Result Expected Performance Sample 11 Positive Positive Acceptable Sample 12 Positive Negative Unacceptable Sample 13 Negative Positive Unacceptable Sample 14 Negative Negative Acceptable Sample 15 Positive Positive Acceptable 2. Based on the laboratory's testing declaration at the time of the survey on October 17, 2023, the laboratory reported approximately 8,000 General Immunology tests results which included ASO analyte during the time the laboratory had unsatisfactory PT testing scores. 3. The TS affirmed that the laboratory received the above unsatisfactory General Immunology ASO PT score.</p>
D6089	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor's review of the laboratory's proficiency testing records and interview with the laboratory technical supervisor on October 17, 2023; it was determined that the laboratory director, failed to ensure that PT samples for General Immunology analyte Antistreptolysin O for the third event of 2022 were tested as required under subpart H. of this part. See D2076