

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1066369	(X3) Date Survey Completed 11/16/2020
Name of Provider or Supplier Los Angeles County	Street Address, City, State 12750 Erickson Ave, Downey, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing performance reports and interview with the laboratory director (LD) and technical supervisor (TS), it was determined that the laboratory failed to verify at least twice annually the accuracy of the Brucella Microagglutination Test (BMAT) the laboratory performed, which is not included in the subpart I of 42 CFR part 493. The findings included: 1. On the date of the survey 11/16/2020 at approximately 2:00 p.m. during proficiency testing and verification of accuracy of test results review, the LD failed to provide documentation for BMAT verification of test results accuracy for two consecutive years: 2018 and 2019. 2. The LD affirmed (11/16/2020 at approximately 4:30 p.m. that no documents were available for the evaluation of the accuracy of BMAT results for the years 2018 and 2019. 3. According to the laboratory testing declaration submitted on the day of the survey (11/16/2020), the laboratory performed General Immunology in 15,030 patient's samples annually including BMAT testing.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of laboratory documentation records and interview with the laboratory director, it was determined that the laboratory director failed to ensure that the verification of the accuracy of test results of non-regulated analytes program was established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: See D-5217

D6118

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(5)

The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.

This STANDARD is not met as evidenced by:
Based on the deficiency cited (D5217), the Technical Supervisor is herein cited for deficient practice in his responsibilities for resolving technical problems revealed through the lack of at least twice annually verify accuracy of the Brucella Microagglutination Test for two consecutive years (2018 and 2019). See D5217.