

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2220076	(X3) Date Survey Completed 03/28/2023
Name of Provider or Supplier Genolab Diagnostics Llc	Street Address, City, State 200 Fairfield Road, Ste 22, Fairfield, NJ	
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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to verify the accuracy of Virology test results obtained from the College of American Pathologists (CAP) for the calendar year 2022. The findings include: 1. The laboratory received a 100 but results were reported with the comments "indeterminate results" and "Unable to obtain Result". 2. There was no documented evidence the laboratory verified: a. "SARS-CoV-2" samples CM-1, and CM-4 events 2022-Bacti-Viral 1, 2022. b. "SARS-CoV-2" samples CM-11, and CM-13 events 2022-Bacti-Viral 3, 2022. 3. The TS confirmed on 3/28/23 at 10:20 am accuracy of the PT results were not verified.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: All proficiency testing evaluation and verification activities must be documented. Based on surveyor review of Proficiency Testing (PT) results and interview with the Technical Supervisor (TS), the laboratory failed to review coded results for Infectious</p>

Disease, Respiratory Testing performed with the College of American Pathologists (CAP) in the calendar year 2022. The findings include: 1. The laboratory received a coded result (Code 26 -Educational Challenge) for Influenza A Subtype, Coronavirus Strain, in event IDR-A 2022 specimens IDR-01,02,03,03 and 05. 2. The laboratory received a coded result (Code 26 -Educational Challenge) for Influenza A Subtype, Parinfluenza Subtype Coronavirus Strain, in event IDR-B 2022 specimens IDR-06,07,08,09 and 10. 3. There was no documented evidence that coded PT results were reviewed. 4. The TS confirmed on 3/28/23 at 11:15 am that the laboratory did not review coded PT results. .