

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0722528	(X3) Date Survey Completed 11/07/2023
Name of Provider or Supplier Allan G Plaut	Street Address, City, State 372 Kingston Ave, Brooklyn, NY	
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
D2025	<p>BACTERIOLOGY CFR(s): 493.823(c)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of API proficiency testing (PT) summary reports and interview with the testing person (TP), the laboratory failed to submit PT results before the required deadline. Findings: 1. PT third event of 2023 was completed, however results were not submitted by the deadline. 2. It was noted that the laboratory's PT results were compared to consensus PT findings and results were acceptable. 3. Confirmed findings by interview with the TP on November 7, 2023, at 11:00 A.M. Refer to 6017.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of API PT summary reports and interview with the TP, the laboratory failed to evaluate, perform, and document corrective action for bacteriology PT scores less than 100%. Findings: 1. 2022 PT first event score = 60%. 2. No documentation of PT corrective action was available for review. 3. Confirmed findings by interview with the TP on November 7th, 2023, at 11:00 A.M. Refer to 6019.</p>

<p>D5291</p>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) policies and procedures as well as interview with the TP, the laboratory failed to comply with the approved QA policies and procedures for monitoring and, when indicated, correct problems. Findings: 1. As per the laboratory procedure manual instructions, a QA review must be performed on a yearly basis. 2. No documentation of 2022 QA performance was available for review. 3. Confirmed findings by interview with the TP on November 7th, 2023, at 11:00 A.M.</p>
<p>D6017</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii)</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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's API PT records and interview with the TP, the laboratory director (LD) failed to ensure that the API PT results were submitted by the required deadline. Refer to D2025.</p>
<p>D6019</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's API PT records and interview with the TP, the LD failed to evaluate, perform, and document corrective action for bacteriology PT scores less than 100%. Refer to D5211.</p>