

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2059412	<b>(X3) Date Survey Completed</b>  11/05/2025
<b>Name of Provider or Supplier</b>  Mendel Warshawsky Md	<b>Street Address, City, State</b>  270 Doughty Boulevard, Inwood, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5221</b>	<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: Based on review of Standard Operating Procedures (SOPs), American Proficiency Institute (API) Proficiency Testing (PT) summary reports, lack of corrective action and remedial action records, as well as interview with the Technical Consultant (TC), the laboratory failed to perform and document plan of correction for all unsatisfactory PT scores. FINDINGS: 1. A review of the PT summary reports from API revealed the following unsatisfactory scores: a. Monocytes Test Analyte: 2023 Third Event = 60% 2024 First Event = 40% 2024 Second Event = 20% 2. There was no documentation of plan of correction performance for the respective unsatisfactory PT scores. 3. This is contrary to instructions indicated in the current, approved SOPs. 4. The TC confirmed the findings on November 5, 2025, at approximately 11:00 A.M.</p>
<b>D6020</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>(e)(5) Ensure that the quality control and 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: Based on review of current, approved SOPs, API PT reports, lack of Quality Assessment (QA) and corrective action records, as well as interview with the TC, the</p>

Laboratory Director (LD) failed to ensure that the QA programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D5221.