

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2222817	<b>(X3) Date Survey Completed</b>  06/30/2025
<b>Name of Provider or Supplier</b>  Invitrox, Inc	<b>Street Address, City, State</b>  76 Tw Alexander Drive, Research Triangle Park, NC	
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>D5213</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2024 and 2025 American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation and interview with technical supervisor (TS) 06/30/25, the laboratory failed to perform and document a review of "not graded" PT results. Findings: Review of 2024 and 2025 API PT records revealed the following "Not Graded" PT sample results; 1. 2024 Immunology/Immunochemistry - 3rd Event - Sample VM-12 for test "Anti-HIV-1/2 (VM) (screen). 2. 2025 Immunology/Immunochemistry - 1st Event - Sample VM-01 for test "Anti-HIV-1/2 (VM) (screen). Review of 2024 and 2025 API PT records revealed no documentation of a review of the 2 "Not Graded" PT results. Interview with TS at approximately 10:15 a.m. confirmed the laboratory had failed to perform and document a review of the 2 "Not Graded" PT results.</p>