

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1011818	(X3) Date Survey Completed 06/17/2025
Name of Provider or Supplier Consultants In Urology Pc	Street Address, City, State 4143 Hylan Boulevard, Staten Island, 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
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: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) records, Standard Operating Procedures (SOPs), lack of corrective action, as well as interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to perform and document corrective action for unsatisfactory PT scores. FINDINGS: a. A review of the API PT report revealed the following unsatisfactory scores: 1. Molecular Parasite - STI Test Analyte: 2024 Second Event = 50% b. There was no documentation of corrective action performance. c. This is contrary to instructions indicated in the current, approved SOPs. d. The TP confirmed the findings on June 17, 2025, at 12:00 P.M.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on direct observation, review of analyzer manufacturer's requirements and SOPs, lack of humidity records, as well as interview with the TP, the laboratory failed to document humidity in the area where on-site laboratory testing was performed. FINDINGS: 1. The Thermo Fisher QuantStudio Real-Time PCR system manufacturer's requirements specified operating humidity range of 15 - 80%. 2. It was noted that humidity was monitored in the laboratory area however there was no documentation of humidity from 2023 through the date of survey. 3. This was contrary to instructions indicated in the current, approved SOPs. 4. The TP confirmed the findings on June 17, 2025, at 12:00 P.M.