

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0916173	(X3) Date Survey Completed 04/07/2022
Name of Provider or Supplier Nshoa	Street Address, City, State 315 East Shore Road Building B, Manhasset, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (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: D5413 Based on the review of manufacturer requirement for chemistry analyzer ACE Axcel Alfa Wassermann and AIA 900 Tosoh BioScience, the laboratory failed to monitor humidity, and establish humidity ranges for the analyzer. Finding: 1. As per user manual of chemistry analyzer ACE Axcel Alfa Wassermann, the manufacturer requirement of humidity range is 20-80% and AIA 900 Tosoh BioScience manufacturer requirement of humidity range is 40-80%. 2. No humidity records were available for review at survey. 3. Confirmed on an interview with laboratory supervisor on 4/7/2022 approximately 1:30pm.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p>

This STANDARD is not met as evidenced by:

Based on lack of of humidity monitoring and documentation, it was determined that the laboratory director failed to implement and maintain the laboratory's quality assessment program. It was confirmed on an interview with laboratory supervisor on 4 /7/2022 about 1:30pm Refer 5413