

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0955743	(X3) Date Survey Completed 03/09/2022
Name of Provider or Supplier Nshoa	Street Address, City, State 48 Route 25a, Suite 102, Smithtown, 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: Based lack of calibration records for both the room temperature and humidity thermometers and an interview with the technical consultant, the laboratory failed to maintain the certification for the thermometers, as required by the manufacturer. FINDINGS: 1. The laboratory failed to maintain the required certification and calibration on room temperature and humidity thermometer in 2021 through survey date for laboratory located in Suite #209 and Suite # 102. 2. The technical consultant confirmed on 3/9/2022 at approximately 1pm, the laboratory failed to maintain the certified calibrated thermometer.</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:
D6021 Based on lack of certification and calibration of thermometer used for room temperature and humidity, 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 technical consultant on 3/9/2022 about 1pm. Refer 5413