

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2160182	(X3) Date Survey Completed 03/10/2022
Name of Provider or Supplier Nshoa	Street Address, City, State 1 Delaware Drive Suite A & Suite B, New Hyde Park, 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 review of the laboratory's, humidity logs for year 2021 and lack of calibration records for both the room temperature/humidity thermometers and an interview with the general supervisor, the laboratory failed to maintain the humidity as required by Sysmex XN 450 for calendar year 2021 and 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. 2.The laboratory failed to ensure that the humidity was within manufacturer requirement range of 20-80% of Sysmex XN 450 for the following days: 2021 March - 10 days April - 5 days May - 10 days June - 4 days 3.The general supervisor confirmed on 3/10/2022 at approximately 2:30pm, the laboratory failed to maintain the humidity requirements and 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</p>

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.

This STANDARD is not met as evidenced by:

Based on review of humidity log for year 2021 and 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 general supervisor on 3/10/2022 about 2:30pm. Refer 5413