

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0684576	(X3) Date Survey Completed 03/04/2022
Name of Provider or Supplier Michael Benhuri Md	Street Address, City, State 1025 N Broadway, Massapequa, 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 on the lack humidity log, the laboratory failed to document daily humidity for the year of 2020, 2021, and up to the survey date. Finding: 1. The laboratory has humidity chart with established range of 15%-75%. The humidity has not been documented for the year 2020, 2021, and up to survey date. 2.The laboratory director and testing person confirmed on an interview 3/4/2022 about 2pm laboratory failed to document humidity.</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 review of the laboratory's humidity log and confirmed in an interview with the laboratory testing person, the laboratory director failed to establish a written QA for all phases for the general laboratory system. Refer to D5413.