

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2034654	<b>(X3) Date Survey Completed</b>  04/08/2022
<b>Name of Provider or Supplier</b>  New York Reproductive Wellness Medicine	<b>Street Address, City, State</b>  300 S Oyster Bay Road, Syosset, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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 endocrine Roche Cobas e411, the laboratory failed to monitor humidity, and establish humidity ranges for the analyzer. Finding: 1. As per user manual of endocrine Roche Cobas e411, the manufacturer requirement of humidity range is 20-80%. 2. No humidity records were available for review. 3. Confirmed on an interview with laboratory supervisor on 4/8 /2022 approximately 11am.</p>
<b>D6021</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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 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 4/8/2022 about 11am. Refer 5413