

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D2034654	<b>(X3) Date Survey Completed</b> 10/10/2024
<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>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Standard Operating Procedures (SOPs) as well as interview with the Testing Person (TP), the laboratory failed to draft, approve instructions for Roche Cobas e411 analyzer control lot validation. FINDINGS: 1. The current, approved SOPs did not include instructions for performing Roche Cobas e411 analyzer control lot validation. 2. Findings were confirmed by interview with the TP on October 10, 2024, at approximately 12:00 P.M.</p>
<b>D5415</b>	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on direct observation, review of thermometer calibration records, as well as interview with the TP, the laboratory failed to perform and document thermometer calibration. FINDINGS: 1. The most recent calibration for traceable thermometer SN# 221156675 utilized for monitoring ambient room temperature where patient specimen testing occurred, expired on January 17, 2024. There was no documentation of calibration performance since expiration. 2. The current, approved SOPs did not include instructions for performing such activity. 3. Findings were confirmed by interview with the TP on October 10, 2024, at approximately 11:30 A.M.