

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2289613	<b>(X3) Date Survey Completed</b>  04/22/2024
<b>Name of Provider or Supplier</b>  Nyu Langone Fertility - Westchester	<b>Street Address, City, State</b>  132 Parkway Road, 2nd Floor, Bronxville, 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>D0000</b>	<p>An announced CLIA exempt-state validation survey was performed on April 22, 2024, by CMS Boston CLIA federal surveyor. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to be in compliance with standard-level CLIA requirements. The findings were reviewed with the regulatory manager during an exit conference at the conclusion of the survey.</p>
<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 record review, review of laboratory written policies and procedures and interview with the regulatory manager, the laboratory failed to have written policies</p>

and procedures that included reportable ranges for one of one analyzer. Findings include: 1. Record review on 04/22/2024 of performance verification records for the Siemens Advia Centaur CP confirmed the laboratory director approved the analyzer for patient use on 01/19/2024. 2. Review of laboratory written policies and procedures on 04/22/2024, revealed no evidence of reportable ranges for the following analytes: Human Chorionic Gonadotropin, Thyrotropin, Estradiol, Follicle Stimulating Hormone, Luteinizing Hormone, Progesterone, and Prolactin. 3. Interview on 02/22/2024 at 01:12 pm with the regulatory manager confirmed the findings above.