

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D1043038	<b>(X3) Date Survey Completed</b>  11/21/2025
<b>Name of Provider or Supplier</b>  Gyn / Endocrine Laboratory	<b>Street Address, City, State</b>  310 Cedar St, New Haven, CT	
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>(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 and staff interview, the laboratory failed to include the reportable ranges for Estradiol and Human Chorionic Gonadotropin (hCG) analytes in the standard operating procedure (SOP) as established and verified by the laboratory director in the subspecialty of Endocrinology. 1. Record review on 11/21/2025 of the laboratory's established SOP revealed " Test Reference Range" as follows for the following analytes: Test Name Ref Ranges a. Estradiol Ovulating Females Follicular ND: 0.0-49.9 pg/mL Midcycle: 350-600 pg/mL Luteal Phase: 20-400 pg/mL HMG</p>

Treatment: 0->50,000 pg/mL b. hCG Positive: 25.1- 500000 mIU/mL Inconclusive: 5.0-25.0 mIU/mL Negative: 0.0 - 4.9 mIU/mL 2. Record review on 11/21/2025 of the final test report for patient #1 revealed reference range as follows for the following analytes: Test Name Reference Range: a. Estradiol Ovulating Females Follicular ND: 0.0-49.9 pg/mL Midcycle: 350-600 pg/mL Luteal Phase: 20-400 pg/mL HMG Treatment: 0->50,000 pg/mL Pregnancy: 1st trimester: 188-2497 pg/mL 2nd trimester: 1278-7192 pg/mL 3rd trimester: 3460-6137 pg/mL b. hCG Positive: 25.1- 500000 mIU/mL Inconclusive: 5.0-25.0 mIU/mL Negative: 0.0 - 4.9 mIU/mL Pregnancy: 1st trimester: 5-288,000 mIU/mL 2nd trimester: 4,060 -165,400 mIU/mL 3rd trimester: 3640 - 117,000 mIU/mL Note: Record review of the patient #1 final test result confirmed lack of documentation of the "pregnancy" period reference ranges for the "estradiol" and "hCG" test analytes in the SOP as mentioned in line item 2 above. 3. Staff interview on 11/21/2025 at 11:00 AM with the laboratory director confirmed the missing "pregnancy" period reference ranges for the "estradiol" and "hCG" test analytes in the SOP as mentioned in 2 above. 4. The laboratory performs 4613 estradiol tests and 2504 hCG tests annually in the subspecialty of endocrinology.