

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2120641	(X3) Date Survey Completed 02/28/2024
Name of Provider or Supplier Gramercy Gynecology Pc	Street Address, City, State 305 7th Ave, 10th Floor, New York, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to enroll in an approved PT program for the bacteriology, mycology, and parasitology sub-specialties. FINDINGS: 1.The laboratory failed to implement bacteriology, mycology, and parasitology PT after initiating patient testing on January 1, 2021. It was noted that the laboratory performed Chlamydia Trichromatic (CT), Neisseria Gonorrhoea (GC), and Trichomoniasis Vaginalis (TV) on the Beckman Dickinson (BD) Max analyzer. 2. The LD confirmed the findings on February 28, 2024, at approximately 10:00 A.M. Refer to D6015.</p>
D2003	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p>

	<p>This STANDARD is not met as evidenced by: Based on review of potassium hydroxide (KOH) and wet mount test records as well as interview with the LD, the laboratory failed to perform twice-year verification for KOH and wet mount slides. FINDINGS: 1. There was no documentation verifying KOH and wet mount slide interpretation accuracy for the three Provider Performed Microscopy (PPMP) providers during calendar years 2021, 2022, and 2023. 2. Approximately 1800 patients were tested by KOH, wet mount slides and results reported for calendar years 2021, 2022, and 2023. 3. The LD confirmed the findings on February 28, 2024, at approximately 10:30 A.M. Refer to D5217.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of testing person (TP) six-month and annual competency evaluation records, lack of training documentation, lack of competency evaluation policy, as well as interview with LD, the LD failed to draft, approve a competency evaluation policy as well as perform, document TP training, six-month, and annual competency evaluations. FINDINGS: 1.The LD failed to draft, approve a competency evaluation policy including the following guidelines: a. Direct observations of routine patient test performance, specimen preparation, processing and testing; b. Monitoring the recording and reporting of test results; c. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; d. Direct observations of instrument maintenance performance and function checks; e. Assessment of patient test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples; f. Assessment of problem solving skills. 2. There was no documentation of TP training, six-month, and annual competency evaluation from January 2021 hire through date of survey. 3. The LD confirmed the findings on February 28, 2024, at 11:30 A.M.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of 2021, 2022, and 2023 calendar year records as well as interview with the LD, the laboratory failed to perform twice-year verification for KOH and wet mount slides for the three providers who performed PPMP testing. Refer to D2003.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an</p>

ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on lack of Quality Assessment (QA) policy and interview with the LD, the laboratory failed to draft, approve a QA policy. FINDINGS: 1. The current, approved Gramercy Gynecology, PC standard operating procedures (SOPs) did not include a QA policy. 2. The LD confirmed the findings on February 28, 2024, at approximately 11:30 A.M.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's current, approved SOP manual and interview with the LD, the laboratory failed to include written instructions for performing the following activities: FINDINGS: 1. Requirements for specimen labeling, criteria for specimen acceptability, and rejection. 2. Microscopic examination for KOH and wet mounts. 3. Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. 4. The LD confirmed the findings on February 28, 2024, at approximately 10:30 A.M.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's current, approved SOPs, QA documentation,

	<p>personnel records, as well as interview with the LD, the LD failed to provide overall management for all phases of moderate complexity testing. FINDINGS: The LD failed to ensure: 1. Enrollment in an approved Health and Human Services (HHS) PT program for the bacteriology, mycology, and parasitology subspecialties after initiating patient testing on January 1, 2021. Refer to D6015. 2. Drafting and approving QA policies for all phases testing. Refer to D6021. 3. Completion and documentation of TP training and competency evaluation. Refer D6029. 4. Drafting and approving SOPs for performing all activities. Refer to D6031.</p>
<p>D6015</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of PT records and interview with the LD, the LD failed to enroll the laboratory in an approved Health and Human Services (HHS) PT program for the bacteriology, mycology, and parasitology subspecialties after initiating patient testing on January 1, 2021. Refer to D2000.</p>
<p>D6021</p>	<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> <p>This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) policy and interview with the LD, the laboratory failed to draft, approve a QA policy for all phases of the general laboratory system. Refer to D5291.</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p>

This STANDARD is not met as evidenced by:
Based on review of TP six-month and annual competency evaluation records, lack of training documentation, lack of competency evaluation policy, as well as interview with LD, the LD failed to ensure that training and competency evaluation were performed and documented for the TP responsible for moderate complexity testing. Refer to D5209.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's current, approved SOP manual and interview with the LD, the laboratory failed to include written instructions for all activities performed. Refer to D5403.