

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0162229	<b>(X3) Date Survey Completed</b> 03/06/2020
<b>Name of Provider or Supplier</b> Upstate Ob/Gyn Associates, Pc	<b>Street Address, City, State</b> 1365 Washington Avenue, Suite 201, Albany, 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>D5203</b>	<p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b> CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of a written laboratory procedure manual and an interview with the office manager, the laboratory failed to to establish and follow written procedures to ensure patient identification, labeling, testing and reporting of results. <b>FINDINGS:</b> The office manager confirmed on March 6, 2020 at approximately 9:45 AM, that the laboratory failed to establish and follow written procedures for patient identification and specimen integrity from collection through reporting test results for the Provider Performed Microscopy Procedures (PPMP) potassium hydroxide (KOH), fern test and wet mounts.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 lack of competency assessment written procedure and an interview with the office manager, the laboratory failed to establish a written procedure for competency assessment for the providers performing PPMP testing. <b>FINDINGS:</b> The office</p>

	<p>manager confirmed on March 6, 2020 at approximately 9:35 AM, that the laboratory failed to establish and follow written procedures for competency assessment based on specific skills for KOH, wet mounts and Fern test; proficiency in using a microscope; ability to detect and identify elements present in a specimen; ability to differentiate significant elements from debris or artifacts and understanding that PPMP specimens are labile.</p>
<p><b>D5217</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 the lack of twice yearly verification and confirmed at survey with the office manager, the laboratory failed to verify the accuracy for KOH, wet mounts and Fern tests.</p>
<p><b>D5401</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on lack of written standard operating procedures (SOP) and confirmed at survey with the office manager, the laboratory failed to establish written policies /procedures for the KOH, wet mount and Fern tests.</p>
<p><b>D5403</b></p>	<p><b>PROCEDURE MANUAL</b> 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 lack of the laboratory's standard operating procedure (SOP) and confirmed at survey with the office manager, the laboratory failed to establish written procedures for: 1. Requirements for patient preparation; specimen collection, labeling, processing. 2. Microscopic examination for KOH, wet mounts and Fern tests 3. Corrective action for inadequate slides. 4. Step-by-step procedure, for KOH, wet mounts, Fern test and interpretation of results. 5. Policy and procedure for unacceptable specimens such as inadequate requisition information and mislabeled /unlabeled specimens.</p>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation and confirmation by the office manager, the laboratory failed to ensure that expiration dates were included on the two bottles of Potassium Hydroxide (KOH) used for KOH testing. Both bottles had the name KOH but did not have an date opened concentration and expiration date.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and confirmation by the office manager, the laboratory failed to ensure that the two KOH reagent bottles with exceeded expiration dates were not used for patient testing. FINDINGS: The surveyor observed two large KOH (10%) bottles by the microscope, with the following lot #'s and expiration dates 1) Lot # 1727511 with expiration date 10-2-2018 2) Lot # 1820407 with expiration date 7-23-2019</p>
<b>D5891</b>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of written Quality Assessment procedure and confirmed at survey</p>

with the office manager, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems.