

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D2088606	<b>(X3) Date Survey Completed</b> 02/26/2020
<b>Name of Provider or Supplier</b> Metro Dermatology Of Ny Pc	<b>Street Address, City, State</b> 40-12 80th Street, Elmhurst, 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 February 26, 2020 at approximately 9:30 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) and wet mount.</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 the lack of a 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</p>

	<p>office manager confirmed on February 26, 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 and wet mounts; 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 PPM 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 records and confirmed at survey with the office manager, the laboratory failed to verify the accuracy for KOH and wet mounts.</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 the of a laboratory 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 and wet mounts 3. Corrective action for inadequate slides. 4. Step-by-step procedure, for KOH and wet mounts and interpretation of results. 5. Policy and procedure for unacceptable specimens such as inadequate requisition information and mislabeled/unlabeled specimens.</p>