

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0670947	<b>(X3) Date Survey Completed</b>  02/14/2024
<b>Name of Provider or Supplier</b>  Marietta Dermatology Associates Pa	<b>Street Address, City, State</b>  111 Marble Mill Road, Marietta, GA	
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>	A recertification survey was performed on February 14, 2024. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
<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 laboratory policy and procedure manual (SOP) review and interview with the clinical supervisor, the laboratory failed to establish and follow a policy and procedure to assess testing personnel (TP) competency containing the 6 required components. Findings include: 1. SOP review revealed a policy and procedure (P&amp;P) failed to assess TP competency for Potassium Hydroxide (KOH) preparations. The P&amp;P addressed the direct observation (DO) of TP performing the test. 2. The P&amp;P lacked the following required components: - monitor recording and reporting of results - review immediate test results, worksheets, quality control (QC), proficiency testing (PT) and preventative maintenance (PM) - DO of instrument maintenance/ function checks - Assessment of test performance thru testing previously analyzed specimens, internal blind testing samples or external PT - Assessment of problem solving 3. An interview with the clinical supervisor, in the downstairs lab #2, at 10:24 a.m., confirmed the aforementioned findings.</p>
<b>D5217</b>	<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</p>

procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and interviews with the clinical supervisor and the lab director (LD), the laboratory failed to verify at least twice annually the accuracy of any test or procedure performed. Findings include: 1. TP document review revealed there were no twice annually peer reviews performed on Staff #2 thru #9; #16 & #17 (CMS 209) for the Potassium Hydroxide (KOH) testing in 2022, 2023, or 2024 thus far. 2. Interviews with the clinical supervisor and LD, in the conference room, on 02/14/24, at 12:05 PM, confirmed the lack of KOH TP peer reviews for the aforementioned dates.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:

Based on observation and testing personnel (TP) interview, the laboratory failed to ensure reagents and solutions not be used after expiration date. Findings include: 1. Observation during the laboratory tour on 02/14/2024 at 11:20 a.m. revealed Marking Tissue Dye Green Lot #21245 expired 09/30/2023 and Marking Tissue Dye Black Lot#21250 expired 09/30/23. Observation during the same tour at 1:20 p.m. on 02/14/2024 revealed there was no replacement dyes available at the time of survey. 2. Interview with TP #14 (CMS 209) in the MOHS laboratory #1 on 02/14/2024 at 11:20 a.m. confirmed the dyes in use had expired and there was no replacement available at the time of survey.