

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 42D0949307	<b>(X3) Date Survey Completed</b> 04/22/2025
<b>Name of Provider or Supplier</b> Dermatology Group, Llc, The	<b>Street Address, City, State</b> 1709 Barnwell Street, Columbia, SC	
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>	An onsite recertification survey was conducted at The Dermatology Group on April 22, 2025. The facility was found to be out of compliance with the Medicare Condition at 42 CFR 493 CLIA Laboratory Requirements. The following is a list of Standard Level deficiencies cited as a result of April 22, 2025, recertification survey.
<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 records review, lack of documentation and staff interview the laboratory failed to establish and follow written policies and procedures to assess the clinical consultant (CC) 1 of 1 reviewed. Findings included: 1. A review of CMS 209 personnel report form reveals one (CC) listed. 2. A review of personnel records reveals the laboratory lack documentation of the required competency assessment for CC. 3. In an interview with TP1 in the office on April 22, 2025, at 3:30 pm the surveyor requested but the laboratory fail to provide competency for the CC.</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 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 record review, lack of documentation, and staff interview, the laboratory</p>

failed to verify the accuracy of the test or procedure twice annually for provider performed microscopy test. Findings included: 1. A review of CMS 116 reveals the laboratory reports subspecialty mycology. 2. A review of records reveals the laboratory failed to document twice annually provider performed microscopy test. 3. The surveyor requested but the laboratory failed to provide accuracy of test or documentation of a procedure used twice annually or any other method used for proficiency testing of mycology on April 22, 2025, at 3:30 pm in an interview with TP1 in the office.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
Based on direct observation and staff interview the laboratory failed to properly monitor temperatures in the laboratory and storage area. Findings included: 1. During the laboratory tour on April 22, 2025, at 2:15 pm, the surveyor observed a traceable thermometer in the laboratory labeled 404090080-06 S/N: 221209411 Due 02 Feb 2024. Calibration with ISO/IEC had expired. 2. Surveyor observed reagents stored in a separate office outside the laboratory. No monitoring device available for storage area on the day of survey. 3. Records review package insert titled Calibration complies with ISO/IEC Cert. No 4040-13-61111 Traceable Certificate of Calibration for Therm./Clock/Humidity Monitor Cal Due Date: 02 Feb 2024. 4. In an interview on April 22, 2025, at 3:30 pm in the office with TP1 the above findings were confirmed.

**D6066**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(4)(ii)

(b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has- (b)(6)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens; (b)(6)(ii)(B) The skills required for implementing all standard laboratory procedures; (b)(6)(ii)(C) The skills required for performing each test method and for proper instrument use; (b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(6)(ii)(E) A working knowledge of reagent stability and storage; (b)(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory; (b)(6)(ii)(G) An awareness of the factors that influence test results; and (b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review of policy and procedure manual, competency records, and interview with testing personnel, it was determined that the laboratory failed to follow policy of evaluating "new hire at six months and annually thereafter" for 1 out of 3 TP records reviewed. Findings included: 1. A review of CMS 209 personnel report form list three TP for high complexity testing. 2. A review of standard operating procedure (SOP #1. 2) titled "Training and Competency Assessment of Non-Pathologist (Processing "Grossing"), page 1, reveals under section II. Procedure: a. #3. New hire processing technicians will spend a minimum of one week observing and being directly observed in the task of specimen "gross description" and sectioning by either the Pathologist or the Laboratory Supervisor. b. #4. A new hire processing technician will be evaluated at six months after completion of training and annually thereafter. c. #5. Evaluations will be done by direct observation (in person) while "grossing." 3. A records review revealed lack of training documentation for TP3 on day of survey April 22, 2025. 4. An interview was conducted on April 22, 2025, at 3:30 pm in the office with TP 1 the above findings were confirmed.

**D6173**

**TESTING PERSONNEL RESPONSIBILITIES**  
CFR(s): 493.1495

The testing personnel are responsible for specimen processing, test performance and for reporting test results.

This STANDARD is not met as evidenced by:  
Based on a record review and staff interview the laboratory failed to document testing personnel responsibilities for high complexity testing for 3 of 3 TP records reviewed. Findings included: 1. A review of CMS 209 personnel report form reveals three testing personnel for high complexity testing. 2. A review of personnel records reveals the laboratory lack documentation of TP responsibilities for high complexity testing as it relates to histopathology. 3. A review of personnel records for CC reveals the laboratory lack documentation of responsibilities for high complexity testing as it relates to histopathology. 4. Surveyor requested during an interview on April 22, 2025, at 3:30 pm in the office with TP 1 but laboratory failed to provide written responsibilities for TP or CC.