

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0686603	(X3) Date Survey Completed 10/23/2025
Name of Provider or Supplier Dermatology Associates Of Georgia Llc	Street Address, City, State 1951 Clairmont Road, Decatur, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) Recertification Survey was completed on October 23, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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: A review of 2023 - 2025 Proficiency Testing Records confirmed that the Laboratory Director failed to enroll in an approved Proficiency Program for the MOHS Testing Procedure. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 WSLI Proficiency Testing Records confirmed that the labortory was not enrolled in a proficiency testing program or peer-to-peer testing program. 2. An exit interview, in the office, with the Office Manager, on October 23, 2025, at 1:00pm, confirmed that the Laboratory Director failed to enroll in an approved Proficiency Program for MOHS Testing Procedure.</p>
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p>

Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

This STANDARD is not met as evidenced by:

A tour of the laboratory and a review of the current procedure manual confirmed that the Laboratory Director failed to ensure all safety procedures and accessibility to safety equipment were available, to the testing personnel, in the clinical laboratory. THE FINDINGS INCLUDE: 1. A review of current procedure manual revealed that all safety procedures were not available, to testing personnel, on the date of survey, October 23, 2025. 2. A tour of the laboratory confirmed that the safety shower was blocked by a fire safety cabinet and multiple boxes. The clean eyewash station was mounted on the dirty sink in use for the disposal of biohazard waste. 3. An exit interview, in the office, with the Office Manager, on October 23, 2025, at 1:00pm, confirmed that the Laboratory Director failed to ensure all required safety procedures and the accessibility to safety equipment were available to testing personnel in the laboratory.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

A review of the 2023 - 2025 Personnel Records confirmed that competencies on the Technical Supervisors were not performed. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 Personnel Records revealed that the required competencies for Technical Supervisor 1 and Technical Supervisor 2, (as listed on Form 209 Laboratory Personnel Report) were not performed. 2. An exit interview, in the office, with the Office Manager, on October 23, 2025, at 1:00pm, confirmed that the required competencies on the Technical Supervisors were not completed.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(a)

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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

A review of Maintenance Records, Personnel Records, Quality Control Records, Temperature/ Humidity Records, and Proficiency Testing Records for 2023 - 2025 confirmed that the laboratory failed to implement or perform quality assurance reviews of all laboratory records. THE FINDINGS INCLUDE: 1. A review of 2023 -2025 Maintenance Records, 2023 - 2025 Personnel Records, 2023 - 2025 Quality Control Records, 2023 - 2025 Temperature/ Humidity Records, and 2023 - 2025 Proficiency Testing Records confirmed that quality assurance reviews were not

performed. 2. An exit interview, in the office, with the Office Manager, on October 23, 2025, at 1:00pm, confirmed that the laboratory failed to implement or perform quality assurance reviews of all laboratory records.

D5417

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

(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:

A tour of the laboratory revealed that the clinical laboratory testing personnel were using expired reagents for patient testing and patient specimen collection. THE FINDINGS INCLUDE: 1. A tour of the laboratory revealed that SurgiPath Clearium Mounting Media, which expired on February 02, 2023, remained in use on the date of survey, October 23, 2025. 2. A tour of the laboratory confirmed that Becton Dickinson Lithium Heparin Vacutainer Tubes, that expired on June 30, 2025, remained in use, on the date of survey, October 23, 2025. 3. An exit interview, in the office, with the Office Manager, on October 23, 2025, at 1:00pm, confirmed that expired reagents, remained in use, by clinical laboratory testing personnel, on the date of survey, October 23, 2025.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

A review of 2023 - 2025 Maintenance Records confirmed that Testing Personnel failed to perform and/ or document maintenance as required by the manufacturer or implement laboratory microscope use protocol procedures. THE FINDINGS INCLUDE: 1. A review of the Microscope Use Protocol Procedure listed the following maintenance performed: - Cleaning of the microscope stage and microscope oculars weekly - Grounding Check to be performed weekly - Calibration of the ocular micrometer annually 2. A review of the Microscope Use Protocol Procedure Item #6 states that "Every action is documented on the Maintenance Record Form. 3. A review of the Leica CM1850 UV Cryostat Manual pp. 38 - 47 lists the following required maintenance: DAILY MAINTENANCE o Remove waste oWear protective gear WEEKLY MAINTENANCE " Disinfect surfaces o Use UVC disinfection o Defrost ANNUAL OR PROFESSIONA MAINTENANCE " Full cleaning and inspection o Check refrigeration system o Inspect and clean parts o Replace seals and lines 4. A review of the Sakura Tissue Tek II User Manual lists the following required maintenance: DAILY MANITENANCE " Wipe the exterior of the sterilizer o Wipe the door gasket and mating surfaces " Inspect the door and dam gaskets for damage. " Drain the reservoir and refill with clean distilled water. o Clean the trays and tray rack " Clean the exterior and gaskets MONTHLY MAINTENANCE " Autoclave prompted maintenance cycle every 28 5. The documentation of completion of the required manufacturers performance, of the items listed above, was not evident in the review of the 2023 - 2025 Microscope Maintenance Logs. 6. Maintenance performance on the

Safety Shower was not performed in the review of the 2023 - 2025 maintenance records. 7. An exit interview, conducted in the office, with the Office Manager, on October 23, 2025, at 1:00pm, confirmed that testing personnel failed to perform and/or document maintenance as required by the manufacturer.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

A tour of the Laboratory facility, a review of the current Procedure Manual, Maintenance Records, Personnel Records, Quality Control Records, Temperature/Humidity Records, Proficiency Testing Records for 2023 - 2025, confirmed that the Laboratory Director failed to provide overall oversight of laboratory operations. Refer to Tags: D2000, D3011, D5209, D5291, D5417, and D5429 for details.