

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D1059597	(X3) Date Survey Completed 07/05/2024
Name of Provider or Supplier Advanced Dermatology Of South Carolina	Street Address, City, State 1700 First Baxter Crossing Ste 101, Fort Mill, SC	
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	An onsite announced CLIA initial survey was conducted on July 5, 2024, at Advanced Dermatology and Cosmetic Surgery Clinic's clinical laboratory by the South Carolina Department of Public Health's (SC DPH) Bureau of Healthcare Systems and Services. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirements for Laboratories. The following is a description of the STANDARD level deficiencies:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 document review, lack of documentation, and staff interview, the laboratory failed to follow its own policy for competency assessment of testing personnel. Findings included: 1 Policy # CP-L 1018 states "Competency Assessment occurs at hire, at six months, and then annually and is performed for each test the testing personnel performs" 2. Document review reveals the lack of initial, 6 months and annual competency assessments. 3. Document review reveals biannual competency records for "KOH and/or Scabies Competency and Proficiency Testing" for the laboratory director (LD), testing personnel 1(TP1), and testing personnel 2 (TP2) for 2024, 2023 and 2022. 4. In an interview with the Office Manger (OM) on July 5, 2024, at 12:00pm in the laboratory breakroom, the findings were confirmed.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an</p>

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:

Based on lack of documentation and staff interview, the laboratory failed to have a written policy of procedure to monitor laboratory systems quality assessments. Findings include: 1. Review of laboratory documents reveals the lack of a written policy and procedure to monitor the laboratory's quality assessments. 2. In an interview with the office manager (OM) on July 5, 2024, at 11:30 am in the laboratory breakroom, the findings were confirmed.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 document review, staff interview, and direct observation, the laboratory failed to monitor the laboratory's environmental conditions. Findings included: 1. The laboratory's environmental records for refrigerator/freezer temperatures lack an acceptable range on 30 of 30 months reviewed. 2. No documentation of the laboratory's room temperature or humidity was available for review. 3. In an interview with the OM in the breakroom on July 5, 2024, at 11:30am, the findings were confirmed. 4. During a tour of the laboratory at 12:00pm on July 5, 2024, the surveyor observed the lack of a temperature or humidity monitoring device in the laboratory.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on document review and staff interview, the laboratory director failed to establish and maintain quality assessments. Findings included: 1. Review of laboratory's procedure manual reveals the lack of a written policy or procedure for ensuring quality assessments are performed. 2. Record review of the laboratory's

documentation reveals the lack of quality assessment monitoring. 3. In an interview with the OM on July 5, 2024, at 11:30am in the laboratory breakroom, the findings were confirmed.