

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0680696	(X3) Date Survey Completed 09/26/2024
Name of Provider or Supplier Advanced Dermatology Of South Carolina	Street Address, City, State 3574 Sunset Blvd, West Columbia, 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 announced CLIA recertification survey was conducted at Advance Dermatology of South Carolina on 09/26/2024 by the South Carolina Department of Public Health (SC DPH). The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The facility was found to be out of compliance with the standards of the CLIA program. The following STANDARD LEVEL DEFICIENCIES were found to be out of compliance.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to monitor and document the temperature of the room that stored pregnancy test. Findings included: 1. During a tour of Advanced Dermatology of South Carolina on 09/26/2024 at 1:00 pm, surveyor observed pregnancy test stored in a room with no thermometer or monitoring device on the day of survey. 2. Review of package insert for McKesson hCG urine test dipstick under the section of storage and stability says, "store as packaged in the sealed pouch at 36-86F/2-30C." 3. In an interview with testing personnel on 09/26/2024 at 1:45 pm in the clerical area, the above findings were confirmed. Key Fahrenheit= F Celsius= C</p>
D3013	<p>FACILITIES CFR(s): 493.1101(e)</p> <p>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.</p>

This STANDARD is not met as evidenced by:
Based on direct observation, lack of documentation and staff interview, the laboratory failed to maintain storage under conditions that ensure proper preservation. Lack documentation of temperature and humidity control for Paraffin blocks and slide storage room. Findings included: 1. During an onsite survey on 09/26/2024 at Advance Dermatology of South Carolina, the surveyor observed the storage room for Paraffin blocks and Histology slides, no monitoring device available on the day of survey. 2. Review of environmental and maintenance logs revealed a lack of documentation for storage room conditions. 3. In an interview with testing personnel on 09/26/2024 at 1:40 pm in the office the above findings were confirmed.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on policy and procedures review, records review and staff interview, the Technical Supervisor failed to evaluate the competency of all testing personnel assuring staff maintain their competency to perform Provider Performed Macroscopics (PPM). 2023 and 2024, 2 of 2 years reviewed. Findings included: 1. Review of policy titled "Verification of PPM Test Results" reveals under responsibilities" it is the responsibility of the Laboratory Director to assure accuracy of PPM testing. 2. Review of CMS 209 reveals four testing personnel (TP) for mycology and parasitology testing. 3. Review of policy titled" Competency Assessment for Testing Personnel" under responsibility: it is the responsibility of the Laboratory Director to assure that competency assessments occur at least annually. 4. Review of Bi-annual KOH and/or Scabies Competency and Proficiency Testing for Laboratory Testing Personnel reveals incomplete forms for 4 of 4 TP competencies lack documentation of reviewing physician or laboratory director. The forms reveal TS lack signature, date and documentation of acceptable or unacceptable proficiency testing competency for 2023 and 2024. 5. Review of Bi-annual KOH and/or Scabies Competency and Proficiency Testing for Laboratory Testing Personnel reveals Laboratory Director (LD) signed and dated his own for 2023 and 2024. 6. In an interview with the testing personnel and office manager on 09/26/2024 at 1:40 pm in the office the above findings were confirmed.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on records reviewed and lack of documentation, the technical supervisor (TS) failed to perform annual evaluations on testing personnel (TP) for 2023. 3 out 4 lack

annual documentation. Findings included: 1. Review of CMS 209 personnel report form revealed four testing personnel (TP). 2. Review of Laboratory Clinical Performance Assessment revealed lack of documentation for 2023 annual assessment for three out of four testing personnel. 3. In an interview with testing personnel on 09/26/2024 at 1:40 pm in the office, the above was confirmed.