

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D1037609	(X3) Date Survey Completed 08/28/2024
Name of Provider or Supplier Carolina Dermatology	Street Address, City, State 933 St Andrews Blvd, Charleston, 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 on 8/28/2024. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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 and interview with staff the laboratory failed to twice annually verify the accuracy of one of one moderately complex test in 2022 and 2023. a. A review of the CMS-116 revealed the laboratory performed the following moderately complex testing: Potassium Hydroxide (KOH) testing. b. The laboratory was asked to provide documentation of verification of accuracy. No documentation was provided. c. An interview with the Practice Manager on 8/28/2024 at 12:10 PM in the breakroom confirmed these findings.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
 Based on record review, direct observations, and interview with staff the laboratory failed to establish an acceptable room temperature from 1/1/2022 to 8/28/2024. a. A review of the laboratory's Room Temperature & Humidity Log for 1/1/2022 to 8/28/2024 revealed "Room Temperature Range 18 [degrees Celsius] to 35 [degrees Celsius] (64.4 [degrees Fahrenheit] to 95.0 [degrees Fahrenheit])". b. On 8/28/2024 at 8:30 AM the surveyor observed the following Tissue Marking Dyes (sampling): Orange, lot number 24071, Expiration date: 3/3/26, Storage Temperature 15-30 [degrees Celsius]; Red, lot number 24067, Expiration date: 3/31/26, Storage Temperature 15-30 [degrees Celsius]; Green, lot number 23289, Expiration date 10/31/2025, Storage Temperature 15-30 [degrees Celsius]; blue, lot number 23345, Expiration date 12/31/2025, Storage Temperature 15-30 [degrees Celsius] c. An interview with the Practice Manager on 8/28/2024 at 12:20 PM confirmed these findings.

D5415

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
 Based on direct observation and interview with staff the laboratory failed to label secondary reagent containers with storage requirements, or preparation/expiration dates. a. During the tour of the laboratory on 8/28/2024 at 8:30 AM the surveyor observed a manual slide stainer filled with staining reagents and a plastic container in a drawer labeled "10% Formalin". The reagents were not labeled with storage requirements or preparation/expiration dates. b. An interview with the laboratory Practice Manager on 8/28/2024 at 11:57 AM in the laboratory confirmed the findings.

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 record review and interview with staff the Technical Consultant failed to document the competency of two of two testing personnel in 2022 and 2023. a. A review of the CMS-116 revealed the laboratory performed the following moderately complex testing: KOH testing. b. The laboratory was asked to provide a policy for the competency assessment. No policy was provided. c. The laboratory was asked to provide competency assessment for testing personnel that perform moderately complex testing. No documentation was provided. d. An interview with the Practice Manager on 8/28/2024 at 10:30 AM in the breakroom confirmed these findings.