

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1100651	(X3) Date Survey Completed 10/06/2021
Name of Provider or Supplier Dermatology Associates Of Georgia	Street Address, City, State 2665 N Decatur Road Suite 650, 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 6, 2021. 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:
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> <p>This STANDARD is not met as evidenced by: Based on maintenance log review and staff interview, the laboratory failed to monitor and document room temperature as required by the manufacturer. Findings include: 1. Maintenance log review revealed the laboratory failed to monitor room temperature in the laboratory as required by the manufacturer of Acuderm, Inc. for Quality control check for 2019, 2020, and thus far 2021. 2. During an interview with the Site Supervisor on October 6, 2021 at approximately 2:30 PM, in the hallway of the office, confirmed there was no room temperature monitoring and documentation for 2019, 2020, and thus far 2021.</p>
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken</p>

when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on temperature and humidity record review and staff interview, the laboratory failed to document corrective action for the humidity. The Findings include: 1. Temperature and humidity record review revealed the laboratory failed to perform a corrective action for the humidity in November 2019(Reference Range: 30%-85% for the following days: 1, 4, 8, 11, 12, 13, 14, 19, 21, 22, 25, and 26). 2. Temperature and humidity record review revealed the laboratory failed to perform a corrective action for humidity in December 2019(Reference Range: 30%-85% for the following days: 1-6, 9-13, 16, 18, 19, and 20). 3. During an interview with the Site Supervisor in the laboratory office on October 6, 2021 at approximately 1:00 PM, it was confirmed that the dates in November and December of 2019, the laboratory failed to perform corrective actions for the humidity.

D6024

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on review of the laboratory record review and staff interview, the laboratory director (LD) failed to ensure that all corrective actions were taken and documented for the laboratory. Findings include: 1. Laboratory record review revealed the LD failed to review and document all correction actions for the following: Temperatures for the Accuderm quality control and the humidity for the laboratory. 2. During an interview with Site Coordinator, in the laboratory office on October 6, 2021, at approximately 2:45 PM, confirmed the LD failed to review and document corrective actions on the humidity for the laboratory.