

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1069247	(X3) Date Survey Completed 10/13/2023
Name of Provider or Supplier Lane Dermatology And Dermatologic Surgery	Street Address, City, State 1210 Brookstone Centre Parkway, Columbus, 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 recertification survey was performed on October 11, 2023. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of temperature and humidity (RH) records and testing personnel (TP) interview, the lab failed to document corrective actions when RH exceeded acceptable limits. Findings include: 1. Review of RH records revealed in June 2022 the RH was out of range 13 of 14 days; October 2022 was out of range 2 of 16 days; February 2023 was out of range 3 of 16 days; and in July 2023 was out of range 4 of 9 days without corrective actions documented. 2. Interview with TP #2 (CMS 209 form) on 10/11/23 at 11:40 AM in the breakroom, confirmed the corrective actions were not documented.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p>

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of testing personnel training and competency documents and an interview with testing personnel, the laboratory director failed to perform initial competency on all testing personnel (TP). Findings: 1. Review of testing personnel training documents revealed the lack of documentation for the initial competency for TP #2 (CMS 209 form). 2. Interview with TP#2 on 10/11/23 in the breakroom at 10:40 am confirmed the lack of documentation.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of testing personnel (TP) competency documents and an interview with testing personnel, the technical supervisor failed to perform semiannual competency on all testing personnel. Findings: 1. Review of TP competency documents provided revealed the lack of a semiannual competency performed on TP #2 (CMS 209 form). 2. Interview with TP#2, on 10/11/23, in the breakroom, at 10:40 am confirmed the lack of documentation.