

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2298315	(X3) Date Survey Completed 03/09/2026
Name of Provider or Supplier Lone Star Dermatology	Street Address, City, State 130 Medical Center Pkwy, Ste 3, Huntsville, TX	
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 survey of the laboratory was conducted on 03/09/2026. The laboratory was found in substantial compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
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 review of laboratory's policies/procedures, twice annual test verification records and staff interview, the laboratory failed to document one of two required annual test accuracy verifications in 2025. Findings included: 1. Review of laboratory's "Proficiency Testing Protocol" policy (no date of approval found) revealed the laboratory did not include the required twice annual frequency of test accuracy verification in its protocols. 2. Review of the laboratory's twice annual test verification records from 2024 and 2025 revealed the laboratory performed test accuracy verification as follows: 2024 Event 2 - dated 11/20/2024 - contained cases 24-071 and 24-072 2025 Event 1 - dated 01/05/2025 - contained cases 25-009 and 25-032 There was no second event in 2025. 3. In an interview on 03/09/2025 at 1050 hours in the laboratory, Testing Person number two (as indicated on submitted form CMS 209) confirmed the findings.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p>

This STANDARD is not met as evidenced by:
Based on review of laboratory's policies/procedures and staff interview, the laboratory failed to ensure one of one procedure manual was approved (signed/dated) by the Laboratory Director prior to start of patient testing. Findings included: 1. Review of laboratory's policies/procedures revealed there was no documentation of signature /date of approval by laboratory director for any of the policies/procedures, or the procedure manual itself. Cross refer to D5217 and D5401. 2. In an interview on 03/09 /2025 at 1050 hours in the laboratory, Testing Person number two (as indicated on submitted form CMS 209) confirmed the findings.

D5417

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

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on surveyor's observations, review of patient test logs/volumes and staff interview, the laboratory failed to ensure expired reagents were not used in patient testing for six of six expired reagents found in the laboratory. Findings included: 1. Surveyor's observations on 03/09/2026 at 1055 hours in the laboratory revealed the following six expired reagents were used in patient testing: Avantic Tissue Marking Die - Black Lot: 182681 Expiration date: 2025-09-30 Avantic Tissue Marking Die - Blue Lot: 183627 Expiration date: 2025-10-31 Avantic Tissue Marking Die - Green Lot: 179632 Expiration date: 2025-09-30 Avantic Tissue Marking Die - Red Lot: 183621 Expiration date: 2025-10-31 Avantic Tissue Marking Die - Yellow Lot: 183624 Expiration date: 2025-09-30 Epredia Signature Series Neg-50 Lot: 128279N Expiration date: 2025-09-08 2. Review of laboratory's patient test logs/volumes revealed the laboratory performed testing on an average of 8-9 cases per month, approximately 40-45 cases starting October 2025 through February 2026. 3. In an interview on 03/09/2025 at 1055 hours in the laboratory, Testing Person number two (as indicated on submitted form CMS 209) confirmed the findings.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on review of laboratory's policies/procedures, maintenance records and staff interview, the laboratory failed to follow its own policy and document monthly microscope maintenance by the tech or physician for five of five months reviewed in 2025 and 2026. Findings included: 1. Review of laboratory's "Maintenance Record for Microscopes" policy (no date of approval found) revealed: "Maintenance of the microscope is done monthly by the lab tech or the physician. A yearly maintenance is

performed on the microscope." 2. Review of the microscope maintenance records from October 2025 through February 2026 revealed there was no documentation of monthly microscope maintenance by the tech or physician for those five months. 3. In an interview on 03/09/2025 at 1050 hours in the laboratory, Testing Person number two (as indicated on submitted form CMS 209) confirmed the findings.