

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2257631	(X3) Date Survey Completed 09/15/2026
Name of Provider or Supplier Elite Dermatology Pllc	Street Address, City, State 2571 Kirby Drive, Houston, 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 09/15/2026. 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.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures manual, submitted Form CMS 209, personnel records and staff interview, the laboratory failed to establish and document competency assessments for two of two supervisory positions within the laboratory, the technical supervisor and general supervisor positions. Findings included: 1. Review of laboratory's policies/procedures manual (last reviewed /approved 11/04/2022) revealed the laboratory did not have protocols in place to evaluate the competency of either its technical supervisor or general supervisor positions. 2. Review of laboratory's submitted Form CMS 209 revealed the laboratory employed one Mohs surgeon who held the positions of technical supervisor, general supervisor and testing person. 3. Review of laboratory's personnel records revealed the Mohs surgeon started performing the Mohs surgeries at this facility in September 2025. Furthermore, personnel records revealed there was no documentation of competency assessment for his technical and/or general supervisory positions. 4. In an interview on 09/15/2026 at 1020 hours in the breakroom, the facility's Manager (as indicated on submitted Entrance/Exit Conference documents) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, twice annual accuracy verification records, test volumes and staff interview, the laboratory failed to follow its own protocols and document required semi-annual test accuracy verification for three of four semi-annual events in 2025 and 2026. Findings included: 1. Review of laboratory's policy "Proficiency Testing" (last reviewed/approved 11/04/2022) revealed: "Semi-annually, the tech or Risk Manager will send two cases containing the original slides, label it(sic) with only the surgical case number, and send it our(sic) for a microscopic examination by a Boardcertified Dermatopathologist." 2. Review of laboratory's twice annual accuracy verification records revealed the test accuracy verification was documented in May 2024 and September 2026. There was no documentation for the three required semi-annual test accuracy verifications in May 2025, November 2025 or May 2026. 3. Review of laboratory's submitted test volumes revealed the laboratory performed testing on 198 samples annually. 4. In an interview on 09/15/2026 at 1115 hours in the breakroom, the facility's Manager (as indicated on submitted Entrance/Exit Conference documents) 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, equipment maintenance logs, patient test records and staff interview, the laboratory failed to document microscope and cryostat maintenance on 08/10/2026, one of twenty-one days of testing from January through August 2026. Findings included: 1. Based on review of laboratory's policy "Laboratory Daily Maintenance" (last reviewed/approved 11/04/2022) revealed: "1. All laboratory equipment is to be cleaned daily when laboratory is in use ... 3. The cryostat will be wiped out with dry gauze call mom and then everything will be wiped down with gauze of 100% isopropyl alcohol. After wiping with alcohol, the machine will be dried with gauze and as soon as the machine goes into the frost cycle will be ready for use. ... 8. Follow procedure for microscope care, and document" 2. Review of laboratory's equipment maintenance logs revealed the laboratory failed to document cryostat and microscope maintenance on 08/10/2026, one of twenty-one days of patient testing from January through August 2026. 3. Review of laboratory's patient test records from 08/10/2026 revealed cryostat and microscope were used for processing of samples from the following patients' cases: AA26-103 AA26-104 AA26-105 AA26-106 AA26-107 AA26-108 AA26-109 4. In an interview on 09/15/2026 at 1135 hours in the breakroom, the facility's Manager (as indicated on submitted Entrance/Exit Conference documents) confirmed the findings.

D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on review of laboratory's quality control (QC) instructions, QC logs, and staff interview, the laboratory failed to document QC of Hematoxylin and Eosin (H&E) histopathology stain reactivity on 08/10/2026, one of twenty-one days of patient testing from January through August 2026. Findings included: 1. Review of the policy from laboratory's "Quality Control Staining" log sheet instructions revealed: "The first case submitted to the Mohs lab which consists of normal tissue will be stained for H&E, documented on the control sheet as the QA." 2. Review of laboratory's QC logs for H&E stain acceptability revealed the laboratory did not document H&E Stain QC on 08/10/2026, one of twenty-one days of patient testing from January through August 2026. 3. Review of laboratory's patient test records from 08/10/2026 revealed H&E Stain was used for processing of samples from the following patients' cases: AA26-103 AA26-104 AA26-105 AA26-106 AA26-107 AA26-108 AA26-109 4. In an interview on 09/15/2026 at 1135 hours in the breakroom, the facility's Manager (as indicated on submitted Entrance/Exit Conference documents) confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, monthly quality assurance (QA) records, submitted test volumes and staff interview, the laboratory failed to document "Monthly Quality Assurance Checklist" and/or "Monthly Patient Quality Assurance Checklist" for ten of twenty months of patient testing from January 2025 through August 2026. Findings included: 1. Review of laboratory's "Quality Assurance Plan" policy (last reviewed/approved 11/04/2022) revealed: "Quality assurance plan is monitored for compliance ..." The policy did not specify the frequency of QA review. 2. Review of laboratory's monthly QA checklists revealed the laboratory had two QA checklists the "Monthly Quality Assurance Checklist" and the "Monthly Patient Quality Assurance Checklist". 3. Further review of the above checklists revealed there was no documentation of either of the two monthly QA checklists for the following ten of twenty months patient testing was performed in 2025 and 2026: January 2025 February 2025 March 2025 April 2025 May 2025 June 2025 July 2025 August 2025 September 2025 May 2026 4. Review of laboratory's submitted test volumes revealed the laboratory performed testing on 198 samples annually. 5. In an interview on 09/15/2026 at 1110 hours in the breakroom, the facility's Manager (as indicated on submitted Entrance/Exit Conference documents) confirmed the findings.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory's submitted Form CMS 209, policies/procedures, personnel delegation of duties records and staff interview, the laboratory director failed to specify in writing the delegation of technical supervisor (TS) and general supervisor (GS) duties for one of one person holding these positions, TS/GS number one. Findings included: 1. Review of laboratory's submitted Form CMS 209 revealed the laboratory had one Mohs surgeon holding the positions TS and GS. 2. Review of laboratory's policies/procedures revealed there were no protocols in place for delegation of TS and GS duties. 3. Review of laboratory's personnel delegations of duties revealed there were no written delegations of duties for positions TS and GS. 4. In an interview on 09/15/2026 at 1020 hours in the breakroom, the facility's Manager (as indicated on submitted Entrance/Exit Conference documents) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services