

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2283764	(X3) Date Survey Completed 08/19/2026
Name of Provider or Supplier Signature Dermatology & Aesthetics	Street Address, City, State 3321 Yucca Drive, Suite 100, Flower Mound, 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 initial survey of the laboratory was completed on 08/19/2026. The laboratory was found in 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.
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 the laboratory's policy, review of the laboratory's daily log, review of patient Mohs logs, and confirmed in interview, the laboratory failed to ensure documentation of intended stain reactivity for hematoxylin and eosin (H&E) stain for 11 of 11 days reviewed from January to June 2026, when patient slides had been made and stained for the assessment of Mohs surgical procedures. Findings included: 1. Review of the laboratory policy titled "Slide Stain Acceptance and Rejection" included the following information: "Policy All stained slides used in diagnostic and laboratory testing will be evaluated against defined acceptance ...Acceptance Criteria Staining Quality: Clear differentiation of tissue components, uniform staining, appropriate contrast, absence of overstaining/understaining." 2. Review of the laboratory log titled "DAILY MAINTENANCE LOG" did not include a daily stain quality assessment for acceptable staining characteristics for H&E from January to June 2026 when patient testing occurred. 3. Review of the patient Mohs log from January to June 2026 included the following 11 days with slides made and H&E stained for the assessment of Mohs surgical procedures: a. 01/28/2026 Mohs Accession #: B26-001 B26-002 b. 02/04/2026 Mohs Accession #: B26-003 B26-004 B26-005 B26-006 B26-007 B26-008 B26-009 c. 02/18/2026 Mohs Accession #: B26-

010 B26-011 B26-012 B26-013 B26-014 B26-015 d. 03/04/2026 Mohs Accession #: B26-016 B26-017 B26-018 B26-018 B26-020 e. 03/18/2026 Mohs Accession #: B26-021 B26-022 B26-023 B26-024 B26-025 B26-026 f. 04/01/2026 Mohs Accession #: B26-027 B26-028 B26-029 B26-030 B26-031 g. 04/15/2026 Mohs Accession #: B26-032 B26-033 B26-034 B26-035 B26-036 h. 04/29/2026 Mohs Accession #: B26-037 B26-038 B26-039 B26-040 i. 05/06/2026 Mohs Accession #: B26-041 B26-042 B26-043 B26-044 j. 06/03/2026 Mohs Accession #: B26-045 B26-046 B26-047 B26-048 B26-049 B26-050 B26-051 k. 06/17/2026 Mohs Accession #: B26-052 B26-053 B26-054 B26-055 B26-056 B26-057 B26-058 4. The Director of Training & Development confirmed the findings during an interview on 08/19/2026 at 1134 hours in the office.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy, review of the laboratory's daily log, review of Mohs patient logs, and confirmed in interview, the laboratory failed to document corrective actions when temperatures fell outside acceptable range for six of eleven operating days for the Cryostat from January to June 2026. Findings included: 1. Review of the laboratory's policy titled "Laboratory Equipment Maintenance" stated: "Pre-Use Checks Set cryostat temperature between -18C and -30C or per manual for optimal cutting." 2. Review of the laboratory's daily log determined the following days from March to June 2026, when documented temperatures fell outside the acceptable temperature range: a. 03/18/2026 Temperature recorded: -32.0C b. 04/01/2026 Temperature recorded: -32.0C c. 04/15/2026 Temperature recorded: -32.0C d. 04/29/2026 Temperature recorded: -32.0C e. 05/06/2026 Temperature recorded: -32.0C f. 06/03/2026 Temperature recorded: -32.0C The surveyor requested documentation of corrective action for days in which documented temperatures were outside the acceptable temperature range. No documentation was provided. 3. Review of the laboratory's Mohs patient logs determined the following patients were assessed while documented temperatures were outside the acceptable temperature range: a. 03/18/2026 Mohs Accession #: B26-021 B26-022 B26-023 B26-024 B26-025 B26-026 b. 04/01/2026 Mohs Accession #: B26-027 B26-028 B26-029 B26-030 B26-031 c. 04/15/2026 Mohs Accession #: B26-032 B26-033 B26-034 B26-035 B26-036 d. 04/29/2026 Mohs Accession #: B26-037 B26-038 B26-039 B26-040 e. 05/06/2026 Mohs Accession #: B26-041 B26-042 B26-043 B26-044 f. 06/03/2026 Mohs Accession #: B26-045 B26-046 B26-047 B26-048 B26-049 B26-050 B26-051 4. The Director of Training & Development confirmed the findings during an interview on 08/19/2026 at 1127 hours in the office. Key: C - Degrees Celsius