

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2295263	(X3) Date Survey Completed 08/24/2026
Name of Provider or Supplier Warthan Dermatology Dallas Pllc	Street Address, City, State 12222 Coit Road Ste 200, Dallas, 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 routine recertification survey of the laboratory was completed on 08/24/2026. 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.
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 the laboratory's policy, review of the laboratory's twice annual accuracy records, and confirmed in interview, the laboratory failed to have documentation of verifying the accuracy of non-regulated histopathology (Mohs) procedures at least twice annually for one of two testing events in 2025. Findings include: 1. Review of the laboratory's policy titled "Proficiency Testing" stated: "Semi-annually, the tech or Risk manager will send two cases containing the original slides, label it with only the surgical case number, and send it out for a microscopic examination by a Board Certified Dermatopathologist." 2. Review of the laboratory's twice annual accuracy records for 2025 determined the laboratory performed one event. On 08/24/2026 at 1044 hours, the laboratory was asked to provide documentation of performing a second twice annual accuracy event in 2025. No documentation was provided. 3. The Dermatologist business partner confirmed the findings in an interview on 08/24/2026 at 1045 hours in the laboratory.
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 direct observation, review of the laboratory's patient Mohs maps, and confirmed in interview, the laboratory failed to ensure tissue marking dye used for Mohs surgical procedures was within the manufacturer's expiration date for 10 of 10 patient testing days from November 2025 to August 2026 (random review). Findings include: 1. Surveyor direct observation on 08/24/2026 at 1012 hours determined the laboratory had tissue marking dyes used for Mohs surgical procedures outside of the manufacturer's expiration date: a. Green Tissue Marking Dye Lot: 184063 Expiration Date: 10/31/2025 b. Blue Tissue Marking Dye Lot: 163941 Expiration Date: 01/31/2025 c. Red Tissue Marking Dye Lot: 162299 Expiration Date: 01/31/2025 2. Review of the laboratory's patient Mohs maps determined tissue marking dyes were used for 10 of 10 patient testing days from November 2025 to August 2026: a. Procedure Date: 11/13/2025 Mohs Accession #: M25-035 M25-036 M25-037 M25-038 b. Procedure Date: 12/19/2025 Mohs Accession #: M25-039 M25-040 M25-041 M25-042 c. Procedure Date: 01/30/2026 Mohs Accession #: M26-001 M26-002 M26-003 d. Procedure Date: 03/06/2026 Mohs Accession #: M26-004 M26-005 M26-006 M26-007 M26-008 M26-009 M26-010 e. Procedure Date: 03/13/2026 Mohs Accession #: M26-011 M26-012 M26-013 M26-014 M26-015 M26-016 f. Procedure Date: 04/09/2026 Mohs Accession #: M26-017 g. Procedure Date: 06/04/2026 Mohs Accession #: M26-018 M26-019 M26-020 M26-021 M26-022 M26-023 h. Procedure Date: 06/30/2026 Mohs Accession #: M26-024 M26-025 M26-026 M26-027 i. Procedure Date: 07/17/2026 Mohs Accession #: M26-029 M26-030 M26-031 j. Procedure Date: 08/06/2026 Mohs Accession #: M26-032 M26-033 M26-034 M26-035 3. The Dermatologist business partner confirmed the findings during an interview on 08/24/2026 at 1043 hours in the laboratory.