

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2300275	(X3) Date Survey Completed 03/04/2025
Name of Provider or Supplier Warthan Dermatology	Street Address, City, State 12255 University Dr # 150, Frisco, 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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5309	<p>TEST REQUEST CFR(s): 493.1241(e)</p> <p>(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, Mohs accession log, Mohs patient slides, Mohs Map, patient final report and confirmed in interview, the laboratory failed to transcribe one of six Mohs accession numbers accurately onto the Mohs map and final report in 12/2024 (random sampling from 12/16/2024 and 12/19/2024). Findings included: 1. Review of the laboratory's policy titled: "LABORATORY PROCEDURE" stated: "1. Tissue is brought to the lab in a Petri dish by the mohs [sic] surgeon with a corresponding [sic] 2. The specimen is given an accession number and logged in the mohs [sic] logbook. Patient name, date, site, diagnosis, stage or layer and number of quadrants per specimen layer." 2. Review of the Mohs accession log for 12/16/2024 and 12/19/2024 revealed six patients had a Mohs procedure. Further review of the accession log revealed the first patient (patient MRN 14280756) on 12/16/2024 was assigned Mohs accession number M24-059 and the second patient (patient MRN MW21445) was assigned Mohs accession number M24-060. 3. Review of patient slides from 12/16/2024 confirmed patient number one was assigned Mohs accession number M24-059. 4. Review of patient number one's Mohs map and patient final report revealed the patient was assigned Mohs accession number M24-060 NOT M24-059. The laboratory failed to transcribe patient number one's Mohs accession numbers accurately onto the Mohs map and final report. 5. During an interview on 03/04/2025 at 12:09 p.m., the Histotechnician stated that accession</p>

numbers were assigned accession numbers chronologically according to collection order. After a review of the findings the Histotechnician confirmed the laboratory failed to transcribe patient number one's Mohs accession numbers accurately onto the Mohs map and final report.

D5413

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

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on direct observation, manufacturer's instructions, the lack of environmental logs, and confirmed in staff interview the laboratory failed to ensure the proper storage conditions of the Olympus BX45 microscope was maintained according to manufacturer's instructions for 10 of 10 months in 2024 (March-December), three of three months in 2025 (January-March). Findings included: 1. During a tour of the laboratory "reading room" on 03/04/2025 at 10:35 a.m., the surveyor observed an Olympus BX45 microscope (Serial #7K17720) on the counter in the testing area. 2. Review of the Olympus BX45 microscope user's manual stated the following: "6 SPECIFICATIONS Item 8. Operating environment Specification Ambient temperature: 5 to 40C (41 to 104 F) Maximum relative humidity: 80% for temperatures up to 31C (88F), decreasing linearly through 70% at 34C (93F), 60% at 37C(99F), to 50% relative humidity at 40C (104F)." 3. The laboratory was asked to provide documentation of environmental logs for room temperature and humidity for March 2024-March 2025. No environmental logs were provided. 4. During an interview on 03/04/2024 at 12:23 p.m., the Practice Manager stated that room temperature and humidity was not monitored in the "reading room". This statement confirmed the laboratory failed to ensure the proper storage conditions of the Olympus BX45 microscope was maintained according to manufacturer's instructions.

D5429

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

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on direct observation, review of manufacturer's instruction manual, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for ensuring 1 of 1 microscope was covered with a dust cover when not in use. Findings included: 1. During a tour of the laboratory on 03/04/2025 at 10:35 a.m., the surveyor observed the Olympus BX45 microscope (Serial# 7K17720) uncovered. The microscope was not in use on the day of inspection. 2. Review of Olympus BX45 microscope instruction manual stated: "2 Maintenance and Storage ... 4. When not

using the microscope, keep it covered with a dust cover." 3. During an interview on 03/04/2024 at 12:23 p.m., the Practice Manager confirmed the laboratory failed to follow manufacturer's instructions for ensuring the microscope was covered with a dust cover when not in use.