

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2012706	(X3) Date Survey Completed 12/07/2022
Name of Provider or Supplier Warthan Dermatology Center	Street Address, City, State 5913 Virginia Parkway Suite 300, Mckinney, 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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: I. Based on direct observation and confirmed in interview, the laboratory failed to ensure expired urine pregnancy test strips were not available for use in patient testing for 1 of 1 box and 1 of 1 vial of NDC Pro Advantage Urine Pregnancy Test Strips and 1 of 1 box of Clinical Guard Pregnancy Urine Test Strips in December 2022. The findings include: A. Laboratory Tour 1. During a tour of the laboratory on 12/07/2022 at 11:40 a.m., the surveyor observed the following on a shelf: 1 box of NDC Pro Advantage Urine Pregnancy Test Strips containing 60 test strips (3 vials of 20 strips);</p>

Lot# HCG0032042; Expiration: 2022-02-28 2. During an interview on 12/07/2022 at 11:40 a.m., the Office Manager confirmed the above findings. B. Patient Restroom Tour 1. During a tour of the patient restroom on 12/07/2022 at 12:27 p.m., the surveyor observed the following in a drawer: 1 opened vial of NDC Pro Advantage Urine Pregnancy Test Strips containing 14 test strips (Lot# HCG9112037; Expiration: 2021-10-31) 1 opened box of Clinical Guard Pregnancy Urine Test Strips containing 20 individually wrapped test strips (Lot# 2010012; Expiration: 2022-09-30) 2. During an interview on 12/07/2022 at 12:27 p.m., the Receptionist confirmed the above findings. II. Based on direct observation, review of manufacturer's instructions, laboratory environmental records, and confirmed in interview, the laboratory failed to monitor the storage temperature for 1 of 1 vial of NDC Pro Advantage Urine Pregnancy Test Strips and 1 of 1 box of Clinical Guard Pregnancy Urine Test Strips in December 2022. The findings include: 1. During a tour of the patient restroom on 12/07/2022 at 12:27 p.m., the surveyor observed the following in a drawer: 1 opened vial of NDC Pro Advantage Urine Pregnancy Test Strips containing 14 test strips (Lot# HCG9112037; Expiration: 2021-10-31) 1 opened box of Clinical Guard Pregnancy Urine Test Strips containing 20 individually wrapped test strips (Lot# 2010012; Expiration: 2022-09-30) 2. Review of the manufacturer's instructions for the NDC Pro Advantage Urine Pregnancy Test Strips and Clinical Guard Pregnancy Urine Test Strips revealed a storage temperature requirement of 2C to 30C (36F to 86F). 3. Review of laboratory environmental records from September to December 2022 revealed no documentation of temperature for the patient restroom. 4. During an interview with a Medical Assistant on 12/07/2022 at 12:47 p.m., the surveyor asked if temperature was monitored in the patient restroom. The Medical Assistant stated temperature was not monitored in the patient restroom. This confirmed the above findings.

D3041

RETENTION REQUIREMENTS
 CFR(s): 493.1105(a)(6)

Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting.

This STANDARD is not met as evidenced by:
 Based on review of laboratory records, patient records, and confirmed in interview, the laboratory failed to retain 1 of 11 Mohs maps (random sampling) from November 2022. The findings include: 1. Review of the laboratory's Mohs log and slides revealed the following patients (random sampling) had a Mohs procedure in November 2022: 11/02/2022 Mohs Accession #s: M22-134, M22-135, M22-136, M22-137, M22-138 11/15/2022 Mohs Accession #s: M22-139, M22-140 Note: M22-140 had 2 maps 11/16/2022 Mohs Accession #s: M22-141, M22-142, M22-143 2. During an interview on with the Office Manager on 12/07/2022 at 11:40 a.m., the surveyor asked where Mohs maps are stored. The Office Manager stated that Mohs maps were scanned into the patient's chart daily. The surveyor requested Mohs maps for the above patients. 3. Review of Mohs maps for the above patients revealed no Mohs map for the following patient: 11/02/2022 Mohs Accession #: M22-135 During an interview with the receptionist on 12/07/2022 at 12:15 p.m., the surveyor requested the original and/or scanned copy of the missing Mohs map. None was provided. 4.

During an interview with the receptionist on 12/07/2022 at 12:23 p.m., the surveyor requested the Mohs map for Mohs Accession#: M22-135 again. None was provided. The laboratory failed to retain patient test reports. This confirmed the above findings.

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:

I. Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory records and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated potassium hydroxide (KOH) procedures at least twice annually for 1 of 1 testing events in 2021 and 2 of 2 testing events in 2022. Findings included: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed KOH procedures. 2. Review of the laboratory's proficiency testing records for 2021 and 2022 revealed the laboratory failed to verify the accuracy of KOH procedures at least twice annually for 1 of 1 testing events in 2021 and 2 of 2 events in 2022. 3. During an interview on 12/07/2022 at 11:27 am, the Histotechnician was asked for documentation of twice annual accuracy for KOH procedures for 2021 and 2022. The Histotechnician stated that there were no twice annual accuracy assessments for 2021 or 2022. This confirmed the above findings. II. Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory policies, laboratory records and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated histopathology (MOHs) procedures at least twice annually for 1 of 1 testing events in 2021 and 2 of 2 testing events in 2022. Findings included: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed histopathology (MOHs) procedures. 2. Review of the laboratory's "Proficiency Testing" policy revealed: "Proficiency Testing Program in the Mohs Micrographic Cutaneous Oncology, this laboratory has instituted an External Quality Control Program. 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 our [sic] for a microscopic examination by a Board Certified Dermatopathologist. NO differential diagnosis will be offered with the specimen. The slide may be labeled "Proficiency Test" by the sending laboratory for the records of the reference laboratory. Upon receipt of the pathology report from the Dermatopathologist, diagnosis of the slide specimen will be matched to the in-house diagnosis by the physician. If the diagnoses match, the reports are attached and placed in "Proficiency Testing" located in the quality control manual. In the event the pathology report from the Dermatopathologist does NOT match the inhouse diagnosis by the physician, an identical slide will be sent, by the tech or risk manager to another outside laboratory chosen from the list below, for microscopic examination. Results of each Proficiency Test will be entered in a log and kept in the laboratory management manual, as part of its permanent records." 3. Review of laboratory records revealed Testing Person-1 (TP-1) and Testing Person-2 (TP-2) performed MOHs procedures. Further review of the records revealed there were no twice annual accuracy assessment records for TP-2 for 1 of 1 event in 2021 and 2 of 2 events in 2022. 4. During an exit telephone interview on 12/15/2022 at 4:00 pm, the Histotechnician confirmed there were no twice annual accuracy assessments for TP-2 in 2021 and 2022.

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, laboratory records, and confirmed in interview, the laboratory failed to follow their own written policy for monitoring cryostat temperatures for 14 of 14 days in 2021 and 46 of 46 days in 2022. The findings include: 1. Review of the laboratory policy "CRYOSTAT MAINTENANCE" revealed: "1. Console temperature is recorded daily. The cryostats should be maintained at -21°C to no colder than -26°C for best Moh's sectioning. Any variance out of range will be recorded and reported to the supervisor, immediately. If the range variance cannot be repaired, the console will not be used until serviced." 2. Review of the Cryostat temperature logs for Cryostats A and B from September 2021 to December 2022 revealed: "1. Console temperature is recorded daily. 2. The cryostats should be maintained at -20C to -30C for best mohs sectioning. Any variance out of range will be recorded and reported to the supervisor, immediately. If the range variance cannot be repaired, the console will not be used until serviced." 3. Further review of Cryostat temperature logs for Cryostats A and B from September 2021 to December 2022 revealed the following documented temperatures for Cryostat A and Cryostat B that were not within the laboratory policy's defined range of -21C to -26C: A. Cryostat A 2021 09/24/2021; Temperature: "-30C" 10/12/2021; Temperature: "-29 C" 10/13/2021; Temperature: "-29C" 11/02/2021; Temperature: "-30C" 11/03/2021; Temperature: "-28C" 11/09/2021; Temperature: "-29C" 11/12/2021; Temperature: "-29C" 11/15/2021; Temperature: "-28C" 12/01/2021; Temperature: "-30C" 12/02 /2021; Temperature: "-30C" 12/14/2021; Temperature: "-30C" 12/16/2021; Temperature: "-30C" 12/29/2021; Temperature: "-30C" 12/30/2021; Temperature: "-30C" 2022 01/12/2022; Temperature: "-30C" 01/13/2022; Temperature: "-30C" 01 /27/2022; Temperature: "-29C" 02/15/2022; Temperature: "-30C" 02/16/2022; Temperature: "-30C" 03/01/2022; Temperature: "-30C" 03/03/2022; Temperature: "-30C" 03/22/2022; Temperature: "-30C" 03/23/2022; Temperature: "-30C" 04/12 /2022; Temperature: "-30C" 04/13/2022; Temperature: "-30C" 05/11/2022; Temperature: "-30C" 05/12/2022; Temperature: "-30C" 05/24/2022; Temperature: "-30C" 05/25/2022; Temperature: "-30C" 06/09/2022; Temperature: "-30C" 06/21 /2022; Temperature: "-30C" 06/22/2022; Temperature: "-30C" 06/23/2022; Temperature: "-30C" 07/19/2022; Temperature: "-30C" 07/20/2022; Temperature: "-30C" 07/21/2022; Temperature: "-30C" 08/03/2022; Temperature: "-30C" 08/16 /2022; Temperature: "-30C" 08/17/2022; Temperature: "-30C" 08/30/2022; Temperature: "-30C" 08/31/2022; Temperature: "-30C" 09/13/2022; Temperature: "-30C" 09/14/2022; Temperature: "-30C" 09/27/2022; Temperature: "-30C" 09/28 /2022; Temperature: "-30C" 09/29/2022; Temperature: "-30C" 10/06/2022; Temperature: "-30C" 10/18/2022; Temperature: "-30C" 10/19/2022; Temperature: "-30C" 10/25/2022; Temperature: "-30C" 10/26/2022; Temperature: "-30C" 11/01 /2022; Temperature: "-30C" 11/02/2022; Temperature: "-30C" 11/15/2022; Temperature: "-30C" 11/16/2022; Temperature: "-30C" 11/17/2022; Temperature: "-30C" 11/29/2022; Temperature: "-30C" 11/30/2022; Temperature: "-30C" 12/01 /2022; Temperature: "-30C" 12/07/2022; Temperature: "-30C" A. Cryostat B 2021 09 /24/2021; Temperature: "-29C" 10/12/2021; Temperature: "-30C" 10/13/2021;

Temperature: "-29C" 11/02/2021; Temperature: "-29C" 11/03/2021; Temperature: "-29C" 11/09/2021; Temperature: "-30C" 11/12/2021; Temperature: "-30C" 11/15/2021; Temperature: "-29C" 12/01/2021; Temperature: "-29C" 12/02/2021; Temperature: "-30C" 12/14/2021; Temperature: "-30C" 12/16/2021; Temperature: "-30C" 12/29/2021; Temperature: "-30C" 12/30/2021; Temperature: "-30C" 2022 01/12/2022; Temperature: "-30C" 01/13/2022; Temperature: "-29C" 01/27/2022; Temperature: "-29C" 02/15/2022; Temperature: "-29C" 02/16/2022; Temperature: "-29C" 03/01/2022; Temperature: "-30C" 03/03/2022; Temperature: "-30C" 03/22/2022; Temperature: "-30C" 03/23/2022; Temperature: "-30C" 04/12/2022; Temperature: "-30C" 04/13/2022; Temperature: "-30C" 05/11/2022; Temperature: "-30C" 05/12/2022; Temperature: "-30C" 05/24/2022; Temperature: "-30C" 05/25/2022; Temperature: "-30C" 06/09/2022; Temperature: "-30C" 06/21/2022; Temperature: "-30C" 06/22/2022; Temperature: "-30C" 06/23/2022; Temperature: "-29C" 07/19/2022; Temperature: "-30C" 07/20/2022; Temperature: "-30C" 07/21/2022; Temperature: "-30C" 08/03/2022; Temperature: "-30C" 08/16/2022; Temperature: "-30C" 08/17/2022; Temperature: "-30C" 08/30/2022; Temperature: "-30C" 08/31/2022; Temperature: "-30C" 09/13/2022; Temperature: "-30C" 09/14/2022; Temperature: "-30C" 09/27/2022; Temperature: "-30C" 09/28/2022; Temperature: "-30C" 09/29/2022; Temperature: "-30C" 10/06/2022; Temperature: "-30C" 10/18/2022; Temperature: "-30C" 10/19/2022; Temperature: "-30C" 10/25/2022; Temperature: "-30C" 10/26/2022; Temperature: "-30C" 11/01/2022; Temperature: "-30C" 11/02/2022; Temperature: "-30C" 11/15/2022; Temperature: "-30C" 11/16/2022; Temperature: "-30C" 11/17/2022; Temperature: "-30C" 11/29/2022; Temperature: "-29C" 11/30/2022; Temperature: "-30C" 12/01/2022; Temperature: "-30C" 12/07/2022; Temperature: "-30C" The laboratory failed to follow their own written policy for monitoring cryostat temperatures. 3. During an interview on 12/07/2022 at 11:27 a.m., the Office Manager confirmed the above findings.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on review of laboratory procedure manual and confirmed in interview, it was

revealed the laboratory failed to have documentation for potassium hydroxide (KOH) procedures. Findings included: 1. Review of the laboratory's procedure manual revealed the manual failed to contain procedures for how to perform KOH procedures. 2. The laboratory was asked to provide documentation of procedure for KOH procedures. No documentation was provided. 3. During an interview on 12/07/2022 at 11:27 am, the Histotechnician confirmed the above findings.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of patient test reports and confirmed in interview, the laboratory failed to include the facility address on 10 of 10 Mohs maps (random review) in November 2022. The findings include: 1. A random review of patient test reports from November 2022 revealed the following 10 Mohs maps missing the facility address: 11/02/2022 Mohs Accession #s: M22-134, M22-136, M22-137, M22-138 Note: The laboratory was unable to retrieve the Mohs map for M22-135 11/15/2022 Mohs Accession #s: M22-139, M22-140 Note: M22-140 had 2 maps 11/16/2022 Mohs Accession #s: M22-141, M22-142, M22-143 2. During a a phone interview on 12/15/2022 at 4:00 p.m., the Histotechnician confirmed the above findings.