Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2102276	07/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Warthan Dermatology Mohs Skin Cancer Surgery	5751 Edwards Ranch Rd Suite 101, Fort Worth, 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 NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.
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 accuracy assessments, and interview, the laboratory failed to perform twice a year accuracy assessment of Mohs for one of three events reviewed. Findings follow. A. Review of the accuracy assessments from 2021 - 2023 showed 1 event performed in 2022. Additional accuracy assessments were requested on June 28, 2023 at 1005 hours but not provided. B. Interview with testing personnel #2, as listed on the CMS form 209, on June 28, 2023 at 1005 hours in the office confirmed one accuracy assessment for Mohs was performed in 2022.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 observation, review of manufacturer's instructions, patient testing logs, and

	interview, the laboratory failed to ensure chemicals and stains used in the Hematoxylin and Eosin (H&E) stain used to process Mohs specimens had not exceeded their expiration date by 28 days for 64 cases for Hematoxylin, and 509 days for an excess of 431 cases for Xylene. Findings follow. A. During a tour of the facility on June 28, 2023 at 1100 hours, surveyor observed: 1. Gill 3 Hematoxylin, Lot 134854, expired 05/31/2023 (expired 28 days), and 2. XS-3 Xylene substitute, Lot 100639, expired 02/04/2022 (expired 509 days), both located in the chemical cabinet. B. Review of the Mohs log showed 64 cases, M23-367 - M23-431, had been processed and tested with Hematoxylin, and in 2023 431 cases had been processed and tested with the Xylene substitute. C. Interview with testing personnel #3 on June 28, 2023 at 1100 hours confirmed the chemical and stain were expired and in use by the laboratory.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the quality assurance forms and interview, the laboratory failed to monitor, assess, and correct problems in the analytic systems per review of the Monthly Quality Assurance Checklist for 18 of 18 months reviewed. Findings follow. A. Review of the Annual Quality Assurance Checklist for Jan - Dec 2022 and Jan - June 2023 showed check marks for: 1. Our Quality Control policies were performed as specified: All reagents, controls, kits, etc. that exceeded their expiration date were discarded (see D5417). 2. Our Proficiency testing policies were followed: All proficiency test results were evaluated. (see D5217). B. Interview with testing personnel #2 as listed on the CMS form 209, on June 28, 2023 at 1145 hours confirmed the 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 the Mohs test report and interview, the laboratory failed to include the name and address of the facility on the Mohs map for ten of ten cases reviewed over a period of 20 months reviewed. A. Review of the Mohs maps showed no name and address of the facility. The following reports were reviewed as listed by date of service and case number: Date of Service Case # 1. 06/22/23 M23-406 2. 05/01/23

	M23-281 3. 03/06/23 M23-161 4. 01/12/23 M23-044 5. 11/14/22 M22-830 6. 09/14 /22 M22-644 7. 07/20/22 M22-475 8. 04/18/22 M22-209 9. 03/07/22 M22-060 10. 10 /18/21 M21-573 B. Interview with testing personnel #3 as listed on the CMS form 209, on June 28, 2023 at 1130 hours confirmed the name and address of the facility were not on the Mohs maps.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of competency evaluations, pre-survey paperwork, and interview, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing in histopathology at least semiannually during the first year for 2 of 2 employees performing inking for four of four competency evaluations in 2022. Findings follow. A. Review of competency evaluations showed no competency evaluations for testing personnel #2 and 3. B. Interview with testing personnel #3, as listed on the CMS form 209, on June 28, 2023 at 1000 hours confirmed there were no competency evaluations performed for the inking. Phone interview with testing personnel #2 on July 11, 2023 at 1315 hours confirmed they began inking at the beginning of 2022.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of educational credentials and interview, the laboratory failed to employ testing personnel that met the educational requirements for two of three testing personnel performing high complexity testing in Histopathology. See D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)

	(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of educational credentials and interview, the laboratory failed to employ testing personnel that meet the educational requirements for two of three testing personnel performing high complexity testing in Histopathology. Findings follow. A. Review of education credentials for testing personnel #2 and 3, on the CMS form 209, showed the following: 1. Testing personnel #2 and 3 had high school diplomas. B. Interview with testing personnel #3, as listed on the CMS form 209, on June 28, 2023 at 0925 hours acknowledged testing personnel #2 & 3 performed inking in Mohs testing. Phone interview with testing personnel #2 on July 11, 2023 at 1315 hours confirmed they began inking at the beginning of 2022.