Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2102276	01/27/2020
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	An entrance conference was held 01/27/2020 with the Medical Assistant. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted on 01/27/2020, this facility was found NOT to be in compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1219 Histopathology 493.1441 Laboratories performing high complexity testing; laboratory director An exit conference was held on 01/27 /2020 with the Medical Assistant. The exit conference attendee was advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided.
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions, cryostat temperature logs, patient reports, and confirmed in interview, the laboratory failed to meet the requirements for the specialty of histopathology as evidenced by: 1. The laboratory failed to document corrective action when temperature for the cryostat was not within the manufacturer's defined acceptable range when cryo-sections were performed for 2 of 19 days in 2018 (01/2018, 03/2018) and 8 of 40 days in 2019 (01 /2019, 02/2019, 03/2019, 06/2019). Refer to D5781, III. This was a repeat deficiency from a recertification survey conducted on 09/12/2017.
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 laboratory policy, proficiency testing (PT)records, and confirmed in interview, the laboratory failed to have documentation of performing semi-annual accuracy assessments for histopathology slide interpretations for 2018 and 2019. Findings: 1. Review of the laboratory's proficiency testing policy revealed: "MOHS MICROGRAPHIC SURGERY SKIN SPECIMENS 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 Testing" by the sending laboratory for the records of the reference laboratory." 2. Review of PT records for 2018 and 2019 revealed PT was performed once in 2018 and once in 2019. The date of the evaluations was not indicated. The top of the evaluation forms only had "Jan/2018" and "January/2019". The forms were signed by the dermatopathologist performing the evaluations with no date indicated. The laboratory failed to have documentation of performing semi-annual accuracy assessments for histopathology slide interpretations in 2018 and 2019. 3. During an interview on 01/27/2020 at 9:28 am, the medical assistant stated that she did not know the exact date of when the semi-annual accuracy assessment in 2018 was performed and she thought the semi-annual accuracy assessment for 2019 was performed sometime in "March 2019." She also stated that those were the only semi-annual accuracy assessments performed in 2018 and 2019, confirming the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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: I. Based on manufacturer's instructions, humidity logs, and confirmed in interview, the laboratory failed to define a humidity range in accordance with cryostat manufacturer's instructions for 12 of 12 months in 2018 and 12 of 12 months in 2019. Findings: 1. Review of Avantik Cryostat QS11 operator's manual revealed a maximum relative humidity of 60% during operation of the cryostat. 2. Review of the laboratory's humidity log in 2018 for cryostats A and B revealed a defined humidity of 60-70%. The laboratory's defined humidity range was not within the manufacturer's defined range for operating conditions. Review of the laboratory's humidity logs in 2019 for cryostats A and B did not include a defined humidity range to ensure humidity was within manufacturer's operating conditions. 3. During an interview on 01/27/2020 at 10:41 am, the medical assistant confirmed the above findings. II. Based

on manufacturer's instructions, humidity logs, and confirmed in interview, the laboratory failed to ensure the room humidity was monitored and documented for cryostats A and B for 15 of 18 days in 2019 (11/2019, 12/2019). Findings: 1. Review of Avantik Cryostat QS11 operator's manual revealed a maximum relative humidity of 60% during operation of the cryostat. 2. Review of the room humidity log for cryostats A and B revealed the laboratory failed to monitor and document the humidity on the following days in 11/2019 and 12/2019: November: 18, 19, 20, 21 December: 3, 4, 5, 6, 7, 9, 16, 17, 18, 19, 20 There was no corrective action documented for the failure to document humidity for the above dates. Note: The laboratory's humidity logs in 2019 for cryostats A and B did not include a defined humidity range to ensure humidity was within manufacturer's operating conditions. 3. During an interview on 01/27/2020 at 10:41 am, the medical assistant confirmed the above findings. III. Based on manufacturer's instructions, room temperature logs, and confirmed in interview, the laboratory failed to define a room temperature range in accordance with cryostat manufacturer's instructions for 12 of 12 months in 2018 and 12 of 12 months in 2019. Findings: 1. Review of Avantik Cryostat QS11 operator's manual revealed a defined temperature range of 5-35C during operation of the cryostat. 2. Review of the laboratory's room temperature log in 2018 for cryostats A and B revealed a defined temperature range of 20-28C. The laboratory was monitoring and documenting temperature in Fahrenheit and not Celsius. The laboratory could not determine if the temperature was within the defined temperature range. Review of the laboratory's room temperature log in 2019 for cryostats A and B revealed a defined temperature range of 20-80C. The laboratory was monitoring and documenting temperature in Fahrenheit and not Celsius. The laboratory could not determine if the temperature was within the defined temperature range. The laboratory failed to define a room temperature range in accordance with cryostat manufacturer's instructions in 2019. 3. During an interview on 01/27/2020 at 10:41 am, the medical assistant confirmed the above findings. IV. Based on review of laboratory policy, manufacturer's instructions, cryostat temperature logs, and confirmed in interview, the laboratory failed to define a temperature range in accordance with cryostat manufacturer's instructions for 12 of 12 months in 2018 and 12 of 12 months in 2019. Findings: 1. Review of the laboratory's Cryostat Maintenance policy revealed: "1. Console temperature is recorded daily. The cyrostats should be maintained at -20*C to no colder than -30*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 Avantik Cryostat QS11 operator's manual revealed: "4-4 TEMPERATURE LIST FOR CRYO-SECTIONING The optimal cutting temperature of a specimen depends on the respective characteristics of the tissue especially on the fat content. The following table won by experience recommends cutting temperatures for some typical applications ... Range B -20 to -30C Muscle Breast without fat Brain Bone Marrow Lungs Intestine Prostata [sic] Cervix Uterus Pancreas Adrenal Skin without fat" 3. Review of the laboratory's temperature chart for cryostat A and B in 2018 and 2019 revealed a defined temperature range of -25C to -30C at the top of the log. On the bottom of the log was a footnote that stated: "1. Console temperature is recorded daily. 2. The cryostats should be maintained at -21*C to -26*C 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 it is serviced." The laboratory had three different defined temperature ranges: -20 to -30C, -25 to -30C and -21 to -26C. 4. During a phone interview on 01/27/2020 at 11:35 am, the laboratory director stated that the defined temperature range was -20 to -30C as stated in the policy and they had gotten rid of the -21 to -26C range. She did not know why there were three separate temperature ranges. V. Based on review of

	laboratory policy, manufacturer's instructions, cryostat temperature logs, and confirmed in interview, the laboratory failed to monitor and document temperature for the cryostat for 1 of 7 days in 2018 (01/2018). Findings: 1. Review of the laboratory's Cryostat Maintenance policy revealed: "1. Console temperature is recorded daily. The cyrostats should be maintained at -20*C to no colder than -30*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 Avantik Cryostat QS11 operator's manual revealed: "4-4 TEMPERATURE LIST FOR CRYO-SECTIONING The optimal cutting temperature of a specimen depends on the respective characteristics of the tissue especially on the fat content. The following table won by experience recommends cutting temperatures for some typical applications ... Range B -20 to -30C Muscle Breast without fat Brain Bone Marrow Lungs Intestine Prostata [sic] Cervix Uterus Pancreas Adrenal Skin without fat" 3. Review of the temperature logs for cryostats A and B revealed the laboratory failed to monitor and document the temperature on the following day in January 2018: January: 12 There was no corrective action documented for the failure to document temperature for the above date. Note: The laboratory's temperature chart for cryostat A and B in 2018 revealed a defined temperature range of -25C to -30C at the top of the log. On the bottom of the log was a footnote that stated: "1. Console temperature is recorded daily. 2. The cryostats should be maintained at -21*C to -26 *C 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 it is serviced." The laboratory had three different defined temperature ranges: -20 to -30C, -25 to -30C and -21 to -26C. 4. During an interview on 01/27/2020 at 10:41 am, the medical assistant confirmed the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policy, Quality Control (QC) logs, and confirmed in interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin (H&E) QC for 126 of 126 days in 2018 (01/2018 through 12/2018) and 94 of 94 days in 2019 (01/2019 through 11/2019). Findings: 1. Review of the laboratory's policy "QUALITY ASSURANCE FOR ROUTINE STAINS" revealed: "1. A quality control slide will be run each day the lab operates. 2. The QC (quality control) slide will be for Hematoxylin and Eosin and/or Toliudine blue. Whichever is in use in the lab. 3. The QC for the H&E will be of normal skin, have a crisp blue nuclei and counter stain with light pink cytoplasm ... The lab director will determine whether the stain is acceptable for the day. Each QC will be logged on the stain QC chart. Any corrections needed for that day will be addressed at that particular time and all changes will be documented." 2. Review of the "QUALITY CONTROL STAINING" log revealed the following: The log had a column for "STAIN" and each day QC was documented with "ok" in the column. The log did not specify the meaning of "ok". The bottom of the log stated: "QUALITY

	ASSURANCE The first case submitted to the mohs lab which consists of NORMAL tissue will be stained for H&E, documented on the control sheet as the QA. This slide will be kept in the file with the case. The Quality control will show, blue nuclei, pink cytoplasm." The following dates in 2018 and 2019 were observed to be documented with "ok": 2018 January: 8, 9, 10, 11, 12, 15, 22 February: 5, 7, 8, 12, 13, 14, 19, 22, 28 March: 5, 9, 12, 13, 14, 15, 20, 26, 27, 28, 29, 30 April: 2, 9, 10, 11, 12, 16, 23, 24, 25, 26, 27 May: 2, 9, 14, 15, 21, 22, 23, 24, 29, 30, 31 June: 1, 4, 11, 12, 13, 14, 15, 22, 25, 26, 27, 28 July: 9, 10, 11, 12, 16, 23, 24, 25, 26, 30, 31 August: 1, 6, 13, 14, 15, 16, 17, 20, 21, 22, 23, 24 September: 5, 6, 7, 11, 12, 13, 14, 25, 27, 28 October: 8, 10, 11, 12, 22, 29, 30, 31 November: 1, 2, 5, 6, 7, 8, 9, 19, 26, 28, 29 December: 3, 4, 5, 6, 7, 10, 18, 19, 20, 27, 28, 31 2019: January: 2, 3, 4, 7, 14, 15, 26, 29, 30, 31 February: 1, 4, 11, 12, 13, 14, 25, 26, 27, 28 March: 1, 8, 11, 12, 13, 14, 15, 25, 26, 27, 28, 29, April: 8, 9, 10, 19, 22, 23, 24, 25, 26, 30 May: 6, 13, 14, 15, 16, 28, 29, 30, 31 June: 3, 17, 24, 25, 26, 27 July: 1, 2, 3, 22, 23, 24, 29, 30, 31 August: 1, 12, 13, 15, 26, 27, 28 September: 10, 11, 12, 24, 25, 26 October: 7, 8, 9, 10, 21, 22, 23, 24, 25 November: 5, 6, 7, 18, 19, 20 The laboratory failed to document the staining characteristics for the H&E stain. 3. Review of test volume records provided by the laboratory included a total annual volume of 1,700 histopathology tests. 4. During an interview on 01/27/2020 at 10:15 am, the medical assistant confirmed the above findings. II. Based on review of the laboratory's policy, Quality Control (QC) logs, and confirmed in interview, the laboratory failed to document for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin (H&E) QC for 12 of 12 days in 2019 (11/2019, 12/2019) Findings: 1. Review of the laboratory's policy "QUALITY ASSURANCE FOR ROUTINE STAINS" revealed: "1. A quality control slide will be run each day the lab operates. 2. The QC (quality control) slide will be for Hematoxylin and Eosin and/or Toliudine blue. Whichever is in use in the lab. 3. The QC for the H&E will be of normal skin, have a crisp blue nuclei and counter stain with light pink cytoplasm ... The lab director will determine whether the stain is acceptable for the day. Each QC will be logged on the stain QC chart. Any corrections needed for that day will be addressed at that particular time and all changes will be documented." 2. Review of the "QUALITY CONTROL STAINING" log revealed the following: The log had a column for "STAIN" and each day QC was documented with "ok" in the column. The log did not specify the meaning of "ok". The bottom of the log stated: "QUALITY ASSURANCE The first case submitted to the mohs lab which consists of NORMAL tissue will be stained for H&E, documented on the control sheet as the QA. This slide will be kept in the file with the case. The Quality control will show, blue nuclei, pink cytoplasm." The laboratory failed to document intended reactivity of the H&E stain on the following dates patients were tested in 2019: November: 21 December: 2, 3, 4, 5, 6, 9, 16, 17, 18, 19, 20 The following are a random sampling of patients from the above-mentioned dates the laboratory failed to document the intended reactivity for the H&E stain: 11/21/2019: M19.690, M19.692, M19.696, M19.697, M19.698, M19.699, M19.700 12/06/2019: M19.731 12/09/2019: M19.732, M19.733 12/20/2019: M19.757, M19.758 3. During an interview on 01/27/2020 at 10:15 am, the medical assistant confirmed the above findings.
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:
I. Based on manufacturer's instructions, humidity logs, patient reports, and confirmed in interview, the laboratory failed to document corrective actions when room humidity was not monitored and documented for cryostats A and B for 15 of 18 days cryo-sections were performed in 2019 (11/2019, 12/2019). Findings: 1. Review of Avantik Cryostat QS11 operator's manual revealed a maximum relative humidity of 60% during operation of the cryostat. 2. Review of humidity logs for cryostats A and B revealed humidity was not monitored and documented on the following days cryo-sections were performed in 11/2019 and 12/2019: November: 18, 19, 20, 21 December: 3, 4, 5, 6, 7, 9, 16, 17, 18, 19, 20 There was no corrective action documented for the failure to document humidity for the above dates. The following are a random sampling of patients that were processed for cryo-sectioning when humidity was not documented for the above-mentioned dates: 11/18/2019 Patient ID: M19.671, M19.672, M19.673, M19.674, M19.675, M19.676, M19.679 11/19/2019 Patient ID: M19.680, M19.681, M19.682, M19.683, M19.684, M19.685, M19.686, M19.687 11/21/2019 Patient ID: M19.690, M19.692, M19.696, M19.697, M19.698, M19.699, M19.700 12/06/2019 Patient ID: M19.731 12/09/2019 Patient ID: M19.732, M19.733 12/20/2019 Patient ID: M19.757, M19.758 3. During an interview on 01/27/2020 at 10:41 am, the medical assistant confirmed the above findings. II. Based on review of laboratory policy, manufacturer's instructions, cryostat temperature logs, patient reports, and confirmed in interview, the laboratory failed to document corrective action when temperature for the cryostat was not monitored or documented for 1 of 7 days cryo-sections were performed in 2018 (01/2018). Findings: 1. Review of the laboratory's Cryostat Maintenance policy revealed: "1. Console temperature is recorded daily. The cyrostats should be maintained at -20*C to no colder than -30*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 Avantik Cryostat QS11 operator's manual revealed: "4-4 TEMPERATURE LIST FOR CRYO-SECTIONING The optimal cutting temperature of a specimen depends on the respective characteristics of the tissue especially on the fat content. The following table won by experience recommends cutting temperatures for some typical applications ... Range B -20 to -30 C Muscle Breast without fat Brain Bone Marrow Lungs Intestine Prostata [sic] Cervix Uterus Pancreas Adrenal Skin without fat" 3. Review of the temperature logs for cryostats A and B revealed the laboratory failed to monitor and document the temperature on the following date in January 2018 when cryo-section was performed: January: 12 There was no corrective action documented for the failure to document temperature for the above date. The following specimens were processed and tested when temperature was not documented: M18.029, M18.030. 4. During an interview on 01/27/2020 at 10:41 am, the medical assistant confirmed the above findings. III. Based on review of laboratory policy, manufacturer's instructions, cryostat temperature logs, patient reports, and confirmed in interview, the laboratory failed to document corrective action when temperature for the cryostat was not within the manufacturer's defined acceptable range when cryo-sections were performed for 2 of 19 days in 2018 (01/2018, 03/2018) and 8 of 40 days in 2019 (01/2019, 02/2019, 03/2019, 06/2019). Findings: 1. Review of the laboratory's Cryostat Maintenance policy

	revealed: "1. Console temperature is recorded daily. The cyrostats should be maintained at -20*C to no colder than -30*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 Avantik Cryostat QS11 operator's manual revealed: "4-4 TEMPERATURE LIST FOR CRYO-SECTIONING The optimal cutting temperature of a specimen depends on the respective characteristics of the tissue especially on the fat content. The following table won by experience recommends cutting temperatures for some typical applications ... Range B -20 to -30C Muscle Breast without fat Brain Bone Marrow Lungs Intestine Prostata [sic] Cervix Uterus Pancreas Adrenal Skin without fat" 3. Review of cryostat A temperature charts in 2018 and 2019 revealed the following dates in which the temperature was not within the manufacturer's defined acceptable limits for cryo-sectioning patient specimens: 01/11/2018: -31 03/09/2018: -31 01/04 /2019: -31 02/01/2019: -31 02/04/2019: -31 02/11/2019: -31 02/27/2019: -31 02/28 /2019: -31 03/01/2019: -31 06/28/2019: -31 There was no corrective action documented for the above dates when the cryostat temperature exceeded the acceptable range as defined by the manufacturer. The following is a random sampling of patient specimens that were processed for cryo-sections when the temperature was not within the acceptable range: 01/11/2018 Patient ID: M18.021, M18.022, M18.023, M18.024, M18.025, M18.026, M18.027, M18.028 03/09/2018 Patient ID: M18.141 01 /04/2019 Patient ID: M19.010, M18.012 02/01/2019 Patient ID: M19.085, M19.086, M19.087 02/11/2019 Patient ID: M19.96, M19.097, M19.098, M19.099, M19.100, M19.101, M19.102, M19.103, M19.104, M19.105, M19.106 Note: the laboratory's temperature chart for cryostat A revealed a defined temperature range of -25C to -30C at the top of the log. On the bottom of the log was a footnote that stated: "1. Console temperature is recorded daily. 2. The cryostats should be maintained at -21*C to -26 *C 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 it is serviced." The laboratory had three different defined temperature ranges: -20 to -30C, -25 to -30C and -21 to -26C. 4. During a phone interview on 01/27/2020 at 11:35 am, the laboratory director stated that the defined temperature range was -20 to -30C as stated in the policy and they had gotten rid of the -21 to -26C range. She did not know why there were three separate temperature ranges. This was a repeat deficiency from a recertification survey conducted on 09/12 /2017.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions, cryostat temperature logs, patient reports, and confirmed in interview, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure quality laboratory services for high complexity analytical systems. Refer to D6082.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)

	The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions, cryostat temperature logs, patient reports, and confirmed in interview, the laboratory director failed to ensure requirements were met for the analytical system, as evidenced by: 1. The laboratory failed to document corrective action when temperature for the cryostat was not within the manufacturer's defined acceptable range when cryo-sections were performed for 2 of 19 days in 2018 (01/2018, 03/2018) and 8 of 40 days in 2019 (01 /2019, 02/2019, 03/2019, 06/2019). Refer to D5781, III. This was a repeat deficiency from a recertification survey conducted on 09/12/2017.