Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1070017	11/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology & Skin Cancer Surgery Center	1790 N Stonebridge Drive, 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	An entrance conference was held 11/20/2019 with the Mohs Tech. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 11/20/2019, 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. 493.1487 Testing Personnel High Complexity Testing An exit conference was held on 11/20/2019 with the Mohs Tech and Laboratory Manager. The exit conference attendees were 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.
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 direct observation, manufacturer's instructions, temperature charts, and in interview with staff, the laboratory failed to define a temperature range for the room in which equipment and supplies were stored and have storage condition requirements for 12 of 12 months in 2018 and 10 of 10 months in 2019. Findings included: 1. During a tour of the Mohs laboratory on 11/20/2019 at 1:20 pm, Transystem Sterile Transport Swab COPAN swabs (quantity of 9; Lot #001B23, expiration date 08/31 /2020) were observed to be stored in the drawer and had a storage requirement of 5 - 25 degrees Celsius (C). The Mohs laboratory had 2 cryostats: Leica CM1510S

	(cryostat #1) and Leica CM1520 (cryostat #2). Review of Leica operator's manual (manufacturer's instructions) stated, "4.1 Installation site requirements: The place of installation must meet the following requirements: Room temperature consistently 18C - 35C." 2. Review of temperature charts from 01/2018 through 10/2019 stated, "Temperature Range- 72." The laboratory did not define a temperature range to ensure all equipment and supplies stored in the Mohs laboratory were within the required temperatures. 3. During an interview on 11/20/2019 at 1:20 pm, the Mohs tech reviewed and confirmed the above findings. II. Based on direct observation, temperature charts, laboratory's procedure manual, and in interview with staff, the laboratory failed to define a consistent temperature range for the primarily used cryostat for 12 of 12 months in 2018 and 10 of 10 months in 2019. Findings included: 1. During a tour of the Mohs laboratory on 11/20/2019 at 1:20 pm, there were 2 cryostats: Leica CM1510S (cryostat #1) and Leica CM1520 (cryostat #2) observed. According to the Mohs tech on 11/20/2019 at 1:20 pm, she stated cryostat #2 is the one primarily used. 2. Review of the temperature charts from 01/2018 through 10 /2019 did not have a temperature range for the cryostat internal temperature, yet it was documented. 3. Review of the laboratory's procedure manual included 3 different policies with 3 different cryostat internal temperature ranges, as follows: "Equipment Quality Control-Cryostat ...2. Temperature range is -20*C to -30*C." "PURPOSE OF FROZEN SECTION: ...The temperature is kept within the recommended cutting range of -19C to -25C." "MOHS PROCEDURE: ...To begin a Moh's procedure the cryostat need to be turned to -20C to -25C." The laboratory did not ensure all of their policies were consistent and it was not known what temperature was the acceptable range. 4. During an interview on 11/20/2019 at 1:20 pm, the Mohs tech reviewed and confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 review of the laboratory's procedure manual, manufacturer's instructions, and maintenance records, the laboratory failed to perform and document maintenance of the Tissue Processor as defined by the manufacturer and with at least the frequency specified by the manufacturer (weekly) for 23 weeks in 10/2018, 11/2018, 12/2018, 09 /2019, 10/2019, and 11/2019. Findings included: 1. Review of the laboratory's procedure for the processor maintenance stated, "7.2 Warm water flush performed weekly" followed by step-by-step instructions. 2. Review of the Sakura Tissue-Tek operators manual (manufacturer's instructions) stated, "WEEKLY MAINTENANCE: Reagent Exchange and Warm Water Flush" followed by detailed step-by-step instructions. 3. Review of a random sampling of Tissue Processor records from 10 /2018, 11/2018, 12/2018, 09/2019, 10/2019, and 11/2019 did not include documentation of the weekly "warm water flush" as defined in the procedure manual and operator's manual. 4. During the exit interview on 11/20/2019 at 2:50 pm, the laboratory manager stated the weekly warm water flush was performed on the Tissue Processor but had not been documented.
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: Based on review of the laboratory's procedure manual, daily hematoxylin and eosin (H&E) quality control (QC) logsheets, test volume records, and in interview with staff, the laboratory failed to ensure documentation of H&E for intended reactivity to ensure predictable staining characteristics, each day of use for 61 of 61 days in 2018 and 61 of 61 days in 2019 (random sampling from 02/2018, 03/2018, 04/2018, 07 /2019, 08/2019, 10/2019). Findings included: 1. Review of the laboratory's procedure manual included "H&E Slide Staining" and did not include documentation of H&E intended reactivity to ensure predictable staining characteristics. 2. Review of the "Daily H&E QC Logsheets" from 02/2018, 03/2018, 04/2018, 07/2019, 08/2019, 10 /2019 included dates, "Tech Initials," Pathologist Initials, Acceptable Y/N, Comments, and Corrective action/tech." For days slides were made and reviewed, "Y" or arrows through the column of "Acceptable Y/N" were documented. The QC logsheets did not include H&E stain defined intended reactivity to ensure predictable staining characteristics. It could not be determined what was an "Acceptable" H&E stain. 3. Review of test volume records provided by the laboratory included a total annual volume of 23,371 histopathology tests. 4. During the exit interview on 11/20 /2019 at 2:50 pm, the laboratory manager reviewed and confirmed the above findings.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, batch control QC logs, patient test report, test volume records, and in interview with staff, the laboratory failed to document reactions of the control slides with each special stain (PAS and Fite) used with each group of patient slides for 1 of 1 day in 2018 (random review 09/27/2018). Findings included: 1. Review of the laboratory's procedure manual for Periodic Acid Schiff's (PAS) and Fite's stains did not include documenting reactions of the controls with each special stain used with each group of patient slides. 2. Random review of the batch control QC logs for PAS stain on 09/27/2018 included "Control Reviewed by:" the laboratory manager and the pathologist with "Acceptable" checked off for Case Numbers (group of patient slides): MB18-9394B, MB18-9422, MB18-9428, MB18-9483, and MB18-9551. Random review of the batch control QC logs for Fite's stain on 09/27/2018 included "Control Reviewed by:" the laboratory manager and the pathologist with "Acceptable" checked off for Case Number (patient slide): MB18-9394. Patient MB18-9394 test report stated, "PAS and Fite stains are negative for

	microorganisms. Control slides are stained appropriately." The procedure did not include the definition of "appropriately" and reactions were not documented. The laboratory did not document reactions of the control slides with PAS and Fite's stains used with each group of patient slides. 3. During the exit interview on 11/20/2019 at 2: 50 pm, the laboratory manager reviewed and confirmed the above findings.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of CMS 209 form, patient test reports, test volume records, and in interview with staff, the laboratory failed to ensure test records included the identity of the personnel who performed the test (grossing) for 6 of 6 patients in 2018 and 2019 (random sampling 09/2018, 10/2018, and 01/2019). Findings included: 1. Review of the CMS 209 form included 2 designated testing persons (TP-6 and TP-7) who performed grossing on patient specimens. 2. Review of the following patient test report from 2018 and 2019 did not include the identity of the personnel who performed grossing, as required: MB18-09394 - patient specimen collected 09/20 /2018; received 09/21/2018; reported 09/27/2018; gross description was documented in 3 parts (A, B, C). MB18-09395 - patient specimen collected 09/20/2018; received 09/21/2018; reported 09/26/2018; gross description was documented in 3 parts (A, B, C). MB18-10750 - patient specimen collected 10/25/2018; received 10/26/2018; reported 10/31/2018; gross description was documented in 2 parts (A, B). MB19-00915 - patient specimen collected 01/23/2019; received 01/24/2019; reported 01/30 /2019; gross description was documented in 1 parts (A). MB19-00916 - patient specimen collected 01/23/2019; received 01/24/2019; reported 01/30/2019; gross description was documented in 1 parts (A). MB19-00917 - patient specimen collected 01/23/2019; received 01/24/2019; reported 01/30/2019; gross description was documented in 1 parts (A). 3. Review of annual test volume records provided by the laboratory included a total of 23,371 histopathology tests. 4. During an interview on 11 /20/2019 at 2:50 pm, the laboratory manager review and confirmed the above findings.
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 the CMS 209 form, competency assessments, and in interview with staff, the technical supervisor failed to evaluate and document performance of 2 of 7 testing persons (TP-6, TP-7) who perform high complexity testing (grossing), at

	least semiannually during the first year (2019). Findings included: 1. Review of the CMS 209 form included TP-6 and TP-7 as individuals who perform grossing of tissue received into the laboratory. 2. Review of "Histology Technician - Competency" for TP-7 included start date of 02/11/2019 and his initial competency assessment was conducted and documented by the laboratory manager on 02/15/2019. Review of "Histology Technician - Competency" for TP-7 for his 6 month competency assessment was conducted and documented by the laboratory manager on 08/12/2019. Review of "Histology Technician - Competency" for TP-6 included start date of 09/13 /2019and her initial competency assessment conducted and documented by the laboratory manager on 09/06/2019. The laboratory manager did not qualify as the technical supervisor and was not listed on the CMS-209 form. Technical supervisor -2 (TS-2) was listed on the CMS 209 form and was the one who provided scientific and technical oversight of the histopathology laboratory. TS-2 did not document performance of TP-6 and TP-7 who performed high complexity testing (grossing), at least semiannually during the first year, as required. 3. During the exit interview on 11 /20/2019 at 2:50 pm, the laboratory manager reviewed and confirmed the above findings.
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 the CMS 209 form, personnel records, and in interview with staff, the laboratory failed to ensure high complexity testing personnel met qualification requirements. The laboratory failed to ensure 2 of 7 testing persons (TP-6, TP-7) met requirements to perform high complexity testing (grossing). Refer to 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 the CMS 209 form, personnel records, and in interview with staff, the laboratory failed to ensure 2 of 7 testing persons (TP-6, TP-7) met requirements to perform high complexity testing (grossing). Findings included: 1. Review of the CMS 209 form included TP-6 and TP-7 as the individuals who perform grossing of tissue received into the laboratory. 2. Review of TP-6 educational documents included a diploma of a Bachelor of Science. Review of TP-7 educational documents included a diploma of a Associate in Applied Science. It could not be determined whether the degrees of TP-6 and TP-7 were in a chemical, physical, biological or clinical laboratory science. 3. During the exit interview on 11/20/2019 at 2:50 pm, the laboratory manager was unable to provide documentation that indicated whether TP-6 and TP-7 had degrees in a chemical, physical, biological or clinical laboratory science, as required.