Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1079340	07/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Mohs Surgery And Dermatology Center	1750 N Randall Rd, Ste 120, Elgin, IL	

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
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 the laboratory's policies, procedures manuals, quality control (QC) logs and interview with the Histology Technician; the procedure manual did not include the following when applicable to the test procedure: *Control procedures. * 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. Findings: 1. Review of the laboratory's policies and procedures manuals revealed that there were no procedures that described what an acceptable Hematoxylin and Eosin (H&E) stain should look like. 2. There

	were no procedures for reporting the gross description of patients' biopsy specimens. 3. Review of QC logs revealed that the laboratory used 2 different logs when it documented the QC of H&E staining. One titled, "H&E Stain Quality Control," and the other titled, "Mohs Surgery and Dermatology Department Center Dermpathology Lab Slide Stain Quality Control." The surveyor could not determine if the 2nd log was for special stains or H&E stains. 4. When the surveyor asked the HT why there were 2 separate QC logs, the HT told the surveyor one is for the Mohs lab, and the other is for the Pathology laboratory. Both were performing H&E staining. However, documentation of the QC was different. 5. There were no results for gross description of tissue specimens from January 2018 through July 23, 2019. When the surveyor asked the HT why, the HT told the surveyor that the laboratory director told him that they did not need to report the "grossing." 6. At 11:30 AM on July 23, 2019, the HT confirmed the surveyor's findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manuals and interview with the Histology Technician (HT), revealed that there was no documentation to show changes in procedures were approved, signed, and dated by the current laboratory director before use. Findings: 1. At 10 AM on July 23, 2019, the surveyor reviewed the laboratory's policies and procedures manuals. 2. There were new procedures with the following titles: a. "Accession procedure (New method)" b. "Change in procedure" c. "Amendment to change of procedure" 4. There was no documentation to show that the laboratory director approved, signed, and dated the new procedures listed above. 5. During survey date July 23, 2019 at 10:30 AM, the HT confirmed the surveyor's findings.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manuals and interview with the Histology Technician (HT), the laboratory failed to maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). Findings include: 1. Review of the laboratory's policies and procedures manuals revealed that older written policies and procedures were kept in the back of the laboratory's policies and procedures manuals. 2. There was no documentation to show when the laboratory discontinued the older written policies and procedures. 3. At 11:00 AM on July 23, 2019, the HT confirmed the surveyor's findings.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290

	Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of policies and procedures manuals, laboratory records, patients' test reports, and interview with the laboratory director; the laboratory failed to monitor and evaluate the overall quality of the postanlaytic systems and correct identified problems as specified in 493.1299 for its histopathology procedures. Findings include: 1. There were no policies that described the laboratory's process for reporting the gross description of biopsy specimens. 2. There was a lack of documentation to show that the gross description of patients' biopsy specimens was documented. 3. There was no documentation of the gross description of patients' biopsy specimens recorded on the final report in the patients electronic medical record. 4. In a telephone interview at 10:35 AM on July 29, 2019, the laboratory director confirmed the surveyor's 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 observation, review of the laboratory policies, procedures manuals, biopsy log, patients' test reports and interview with the laboratory director (LD); the test report failed to indicate the following: *The test report date. *The test performed *The test result, and if applicable, the units of measurement or interpretation, or both. Findings include: 1. In a policy titled, "Accessioning and procedure (New method)", under "Purpose" it states, "To assign responsibility and clarify procedures for accession of specimens.... Mark all pertinent information into the log book to include... Initial of the histotech who will perform the grossing." 2. The surveyor selected a total of 10 patients names from the biopsy testing log. There was no documentation of the gross description for 10 of 10 patients' names selected from the biopsy log. 3. At 12:00 PM on July 23, 2019, the surveyor observed that there was no documentation of the gross description of biopsy specimens documented in the biopsy log from January 2018 to July 23, 2019. 4. Review of 10 patients' test reports selected from the biopsy log revealed that the laboratory did not document the gross description of the patients' specimens when it reported the results of biopsy specimens in the patients' electronic medical record. 5. In a telephone interview at 10:35 AM on July 29, 2019, the laboratory director confirmed the surveyor's findings, stating that he did not know he was supposed to report the grossing results.

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 procedures manuals, patients' test reports and personnel records; the laboratory director failed to be responsible for the overall management and direction of laboratory services in accordance with 493.1445 of this subpart. Findings include: 1. The laboratory failed to perform and document the gross description of biopsy specimens from January 2018 through July 23, 2019. See Dtags 6095 and 6098. 2. There was no documentation to show that the laboratory director assessed the competency of 2 of 5 Mohs surgeons in the laboratory. See Dtag 6103 3. There was no documentation to show that the laboratory director assigned the position of testing person of Mohs to 2 of 5 Mohs surgeons in the laboratory. See Dtag 6107
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manuals, laboratory records, patients test records and interview with the laboratory director; the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for its histopathology procedures. Findings include: 1. The procedures indicates that the laboratory director changed the laboratory's procedures manual, removing pertinent information from the final results of the test report. 2. Review of laboratory records revealed that testing personnel did not document the gross description of patients' specimens in the laboratory biopsy log as instructed. 3. Review of patients test records revealed that the laboratory did not report the gross description of patients' specimens on the final reports of patients' test reports from January 2018 to July 23, 2019. See Dtag 5803 4. At 10:35 AM on July 29, 2019, the laboratory director confirmed the surveyor's findings.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of laboratory policies, procedures manuals, patients' test reports and interview with the laboratory director; the laboratory director failed to ensure that reports of test results include pertinent information required for interpretation. Findings include: 1. The laboratory procedures included a procedure titled "Amendment to change of procedure. It states, "We have removed the following,

	except in the case of excisions: *Title of document: Final Diagnosis Report *Case Number *Complete address of the provider location *Added skin before each site description *Gross Description *Grossing personnel" 2. Review of 10 patients test reports revealed that there was no gross description of the patient's specimen, documented on the final report of 10 of 10 patients' test reports reviewed. See Dtags 5803 and 5805 3. In a telephone interview at 10:35 AM on July 29, 2019, the laboratory director confirmed the surveyor's findings.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of Laboratory Personnel Report (FORM 209), laboratory procedures, personnel records and interview with the Histology Technician (HT); the laboratory director failed to ensure that policies and procedures are established for monitoring testing personnel to ensure that they are competent and maintain their competency to perform test procedures and report test results. Findings include: 1. The laboratory listed a total of 10 testing personnel on FORM 209. 5 persons cut and processed Mohs tissue specimens. 5 others read Mohs slides (Mohs surgeons). 2. Review of laboratory procedures revealed that there was a competency procedure for the Mohs surgeons. 3. Review of personnel records revealed that there was no competency assessment performed on 2 of 5 Mohs surgeons. 4. At 10:30 AM on July 23, 2019, the HT confirmed the surveyor's findings.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of Laboratory Personnel Report (FORM 209), laboratory policies, procedures manuals, personnel records and interview with the Histology Technician (HT); the laboratory director failed to specify in writing the responsibilities and duties of each person engaged in the performance of each phase of the testing process and whether director review is required prior to patient test results. Findings include: 1. There were a total of 10 testing personnel listed on FORM 209, that was submitted on the day of survey. 2. Review of the laboratory policies and procedures manual revealed that the laboratory director did not specify in writing the responsibilities and

	duties and which examinations performed for 2 of 10 testing personnel listed on FORM 209. 3. Review of personnel records revealed that the laboratory director did not specify in writing the responsibilities and duties and which examinations performed for 2 of 10 testing personnel listed on FORM 209 4. At 10:30 AM on July 23, 2019. the HT confirmed the surveyor's findings.