Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D2136624	01/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Integrated Dermatology Of 19th Street Llc	1145 19th Street Nw Suite 301, Washington, DC	

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 record review and interview with the histotechnician, the lab did not ensure that the written hematoxylin and eosin stain set up attached to the wall above the stain line agreed with the position of stain solutions in the stain line and agreed with the written description of the stain line in the written procedure manual. Findings: 1. The stain chart describing the order of the stain line posted on the wall above the stain line states that the second reagent is hematoxylin, but the second reagent in the stain line is water and the stain chart in the written procedure states that water is both the third and forth reagent; 2. The chart posted on the wall and the chart in the written procedure

	and the stain set up do not agree with one another; and 3. This was confirmed with the histotechnician during interview at approximately 2:00 p.m. on the day of survey.
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 observation and interview, the laboratory (lab) did not document preventive maintenance performed on the timers used during staining of MOHS surgery slides and the microscope used for microscopic analysis of slides. Findings: 1. The lab written procedure states to check the timer for accuracy, but the lab did not have records showing that the timer accuracy was checked in 2018 and 2019; 2. The lab written procedure stated that the microscope was periodically cleaned, but did not have records showing that microscope cleaning was performed in 2018 and 2019; and 3. This was confirmed with the lab director during interview at approximately 2:00 p. m. on the day of survey.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: A. Based on record review, the laboratory (lab) did not have a written procedure to document problems, notify the lab director, take corrective actions and monitor those corrections to ensure problem resolution. Findings: 1. The written procedure did not include instructions to document, report, correct and monitor problems identified during the total histology testing process (specimen collection, staining, microscopic analysis and reporting); and 2. The lab did not have written procedures to review, investigate and if needed, correct discrepant findings that may occur during peer review of MOHS cases. B. Based on record review, observation and interview with the histotechnician, the lab did not identify errors in histology patient testing records and labeling. Findings: 1. The laboratory performs a clerical check for each day of MOHS surgery, the check is to ensure that microscopic slides, MOHS log sheet and MOHS map do not show clerical and labeling discrepancies. 2. The clerical checks did not identify problems in 2019; 3. Observation of records and slides for October 4, 2019 identified the following errors in test records; 4. The last name of Patient #1 was misspelled, the second and third letters in the patient name were transposed, the name was spelled differently between the MOHS log and the MOHS map; 5. This was confirmed with the histotechnician during interview at approximately 2:00 p.m. on the day of survey; 6. The case number on the MOHS maps did not agree with the case numbers on the patient slides and the MOHS logs for both Patient #2 and Patient #3. In addition the case number on the MOHS map for Patient #2 was the same case number written on the MOHS map for Patient #3; and 7. This was confirmed with the histotechnician during interview at approximately 2:00 p.m. on the day of survey.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory stain quality control record did not show that the quality control review performed on the first slide stained, each day of testing, was checked for characteristic staining by the surgeon performing the microscopic analysis. Findings: 1. The laboratory stain quality control record has a column labeled histotechnician quality check, and a column labeled "laboratory director", but the column labeled laboratory director, who is also the MOHS surgeon, did not specify that the lab director column was a clerical review or was initialed by the MOHS surgeon to show stain acceptability; 2. The lab did not have a written procedure describing the review of the quality control slide, and the characteristics of the stain that the reviewer observes to ensure stain quality; and 3. This was confirmed during interview with the lab director at approximately 2:00 p.m. on the day of survey.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: A. Based on record review and interview with the laboratory (lab) director approximately 2:00 p.m. on the day of survey, the lab did not have a written procedure for submission of MOHS surgical slides and records for peer review (proficiency testing). Findings: 1. The laboratory submits MOHS cases for peer review, the review performed for 2019 was submitted on January 8, 2020, and it was explained by the lab director that the cases were chosen to ensure (by date) the entire year of 2019 was represented; and 2. The lab did not have a written procedure to describe how often cases are submitted, and how the lab ensures that the cases represent testing throughout the year of review. B. Based on record review, observation and interview, the histology laboratory did not perform and complete the quarterly quality control checklist for 2018 and 2019. Findings: 1. The written procedure states that the lab will complete the quality assurance checklist quarterly; 2. The lab did not have quality assurance checklists for both 2018 and 2019; and 3. This was confirmed during interview with the lab director at approximately 2:00 p.m. on the day of survey. C. Based on record review and interview, the histology laboratory (lab) did not complete the weekly clerical review of MOHS surgery cases by identifying the reviewer as indicated on the form used to document the clerical check. Findings: 1. The lab performs a clerical check after each day of MOHS surgery to ensure information written on the patient slides, the MOHS surgery log and the MOHS map are accurate and reliable; 2. The bottom of the clerical review record has a place for the reviewer

	to identify who performed the review, but this was not filled in for both the 2019 and 2018 record; and 3. This was confirmed with the lab director during interview at approximately 2:00 p.m. on the day of survey.