Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D2136624	07/02/2018
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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on observations and interview with the Mohs Technician and a management staff on July 2, 2018 at approximately 1:30 PM and 2:00 PM respectively, the laboratory failed to ensure that an adequate space is provided for staining Mohs surgery slides. The findings included: 1. The laboratory uses a moveable staining station with a table top hood (G-Series Containment Hood). The staff moves the staining station from storage to the laboratory / patient exam room /Mohs room on the days the laboratory performed Mohs procedure. The staining station is placed behind a big unmovable examination chair. 3. The station is on top of a very low table. The Mohs Technician demonstrated to the surveyor how the staff process the slides, by squatting. In addition, due to the height of the table and the position of the exam chair, the lighting inside the hood is inadequate. There is very little room between the chair and the processing station. 4. Interview with the Mohs Technician revealed that he/she had been able to use the station with some difficulty. 5. The lack of adequate space was discussed with management staff at the time of the exit conference.
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 observation conducted on July 2, 2018 at approximately 11:30 AM and confirmation by interview with the laboratory's Mohs Technician, at the time of observation, the laboratory's policies and procedure manual failed to include a protocol for labeling jars containing working staining materials to identify the content. None of the jars containing the staining materials for seven (7) of the seven (7) staining solutions were labeled with the content (95 percent alcohol; hematoxylin; tap water; scotts bluing reagent; eosin; absolute alcohol; and histoclear). Cross-reference D5415.
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 the review of the laboratory's policies and procedures manual, interview with the Mohs Technician on July 2, 2018 at approximately 12:00 Noon, the laboratory failed to ensure that the Mohs surgery specimen processing procedures are approved by the current laboratory director. Findings include: 1. None of the procedures in the laboratory's Mohs procedure manual were signed and approved by the current laboratory director. 2. Review of the procedures revealed signature of a director that no longer the director of this laboratory. Note: The laboratory adopted the procedure from another laboratory that used to be owned by the same provider. However, no evidence that the current Laboratory Director approved and signed it for this laboratory. 3. Interview with the Mohs Technician confirmed the lack of approval by the current Laboratory Director.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on observations conducted on July 2, 2018 at approximately 11:30 AM and confirmation by interview with the laboratory's Mohs Technician, at the time of observation, the laboratory failed to ensure that each jar containing working staining material is labeled to identify the content. None of the jars containing the staining materials for seven (7) of the seven (7) stain solutions were labeled with the content (95 percent alcohol; hematoxylin; tap water; scotts bluing reagent; eosin; absolute alcohol; and histoclear) The findings included: 1. Review of the laboratory's procedure for staining using Hematoxylin and Eosin stain revealed that the laboratory uses the following to stain Mohs surgery specimens: 95 percent (percentage) alcohol; hematoxylin; tap water; scotts bluing reagent; eosin; absolute alcohol; and histoclear. These staining materials were observed in approximately thirteen (13) jars that were kept under a hood. At the time of observation, none of the jars containing the aforementioned chemicals or water was labeled. 2. Further review of the procedure failed to include instructions for labeling jars containing working solutions. 3. Interview with the Mohs Technician confirmed the lack of labeling to identify each working staining solutions. According to the interview, the staff indicated that he/she knows what is in each jar.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on the review of records (manufacturer's instructions and the laboratory's policies and procedures) and interview with the Mohs Technician on July 2, 2018 at approximately 2:00 PM, the laboratory failed to ensure that a protocol had been developed for changing the filter for one (1) of the one (1) hood the laboratory uses (G-Series Containment Hood). The findings included: 1. Review of AVANTIK BIOGROUP (the manufacturer of G-Series Containment Hood) revealed a recommendation for changing filters depending on the type of the filter. According the staff the filter is a charcoal filter and the manufacturer recommends replacing it every 4-6 month. 2. Review of the laboratory's policies and procedure did not provide protocol for changing the filter. 3. Review of a maintenance sticker on the hood revealed that the hood filter was last replaced on 9/4/15, prior to the hood being in use at this laboratory (January 2018). 4. Interview with the Mohs Technician confirmed the lack of protocol for changing the filter based on the manufacturer's instructions.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.

	This STANDARD is not met as evidenced by: Based on observations and interview with the Mohs Technician and a management staff on July 2, 2018 at approximately 1:30 PM and 2:00 PM respectively, the Laboratory Director failed to ensure that adequate space is provided for staining Mohs surgery slides. Cross-reference D3001.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: A. Based on observations conducted on July 2, 2018 at approximately 11:30 AM and confirmation by interview with the laboratory's Mohs Technician, at the time of observation, the Laboratory Director failed to ensure that the laboratory's policies and procedures manual included protocol for labeling jars containing working staining materials to identify the content. None of the jars containing the staining materials for seven (7) of the seven (7) staining solutions were labeled to identify the content (95 percent alcohol; hematoxylin; tap water; scotts bluing reagent; eosin; absolute alcohol; and histoclear). Cross-reference D5403. B. Based on the review of records (manufacturer's instructions and the laboratory's policies and procedures) and interview with the Mohs Technician on July 2, 2018 at approximately 2:00 PM, the Laboratory Director (LD) failed to ensure that a protocol had been developed for changing the filter for one (1) of the one (1) hood the laboratory uses (G-Series Containment Hood). Cross-reference D5435.