Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D2136624	08/30/2024
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 review of the written procedure manual and interview with laboratory staff, the lab failed to have written procedures for all areas of the lab when MOHS testing was performed. Findings: Refer to D5791, D5805, and D5891 1. The laboratory tests for skin carcinoma from tissue samples obtained during MOHS surgery. 2. The lab failed to have step by step instructions for documenting the MOHS patient identification number on the patient case log, patient slides, MOHS maps, and the patient final report with the first letter of the MOHS surgeon last name followed by a sequence of numbers. 3. The MOHS tech stated that the letter "C" before the numbers

	was for the first letter of the MOHS surgeon last name performing testing that day and sometimes he added the first letter of the surgeon last name on the MOHS case log, patient slides, and MOHS maps and sometimes he did not. 4. The MOHS tech confirmed on 9/6/24 at 1:00 PM by phone call that the lab failed to have step by step instructions for documenting the MOHS patient identification number on the patient case log, patient slides, MOHS maps, and the patient final report with the first letter of the MOHS surgeon last name followed by a sequence of numbers.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, The lab failed to perform quality assessment procedures when performing MOHS surgical procedures. Finding: 1. The laboratory tests for skin carcinoma from tissue samples obtained during MOHS surgery. 2. Review of the MOHS log, patient maps, and case slides tested on 11/30/23 showed that one out of three patients MOHS case identification numbers did not match throughout the analytic process. 3. Patient "A" perfromed on 11/30/23 case number on the MOHS log was C23-124, on the patient map the case number was 23-124, and on the case slides the number was 23-124. 4. The MOHS tech stated that the letter "C" was for the first letter of the MOHS surgeon last name performing testing that day. 5. The MOHS tech confirmed on 9/6/24 at 1:00 PM by phone call that the lab did not maintain quality assessment procedures when performing MOHS surgery.
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 review of patient final reports and interview with laboratory staff, the lab failed to ensure that patient final reports showed accurate and reliable information. Findings: A. 1. The laboratory tests for skin carcinoma from tissue samples obtained during MOHS surgery. 2. Review of five patient final reports tested on 3/8/23 showed one patient's final report did not have the correct MOHS identification number nor the location name and address where the test was performed. 3. One final report from 3/8 /23 showed the MOHS identification number for "Patient B" was C24-37. 4. The MOHS log on 3/8/23 showed that "Paient B" MOHS identification was C23-37, and the MOHS case slides showed the identification number was C23-37. 5. Patient "B"

	MOHS map from 3/8/23 showed that the case was performed at "5530 Wisconsin AVE, Chevy Chase Maryland and the case number was C22-37. 6. The MOHS tech confirmed on 9/6/24 at 1:00 PM by phone call that the lab did not maintain patient final reports with accurate and reliable information. B. 1. The laboratory tests for skin carcinoma from tissue samples obtained during MOHS surgery. 2. Review of the MOHS log, patient maps, and case slides on 11/30/23 showed that one out of three patients case identification numbers did not match throughout the analytic process. 3. Patient "A" perfromed on 11/30/23 case number on the MOHS log was C23-124, on the patient map the case number was 23-124, and on the case slides the number was 23-124. 4. Patient "A" final report did not have the MOHS case identification number on the report. 4. The MOHS tech stated that the letter "C" infront of the numbers was for the first letter of the MOHS surgeon last name performing testing that day. 5. The MOHS tech confirmed on 9/6/24 at 1:00 PM by phone call that the lab did not maintain patient final reports with accurate and reliable information.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the "Quarterly Slide and Case Review" and interview with lab staff, the lab failed to identify and correct problems during the post assessment process. Findings: 1. The laboratory tests for skin carcinoma from tissue samples obtained during MOHS surgery. 2. Review of the "Quarterly Slide and Case Review" dated 4/12/23 showed the lab director failed to identify discrepancies from Patient "C" review. 3. Patient "C" had MOHS surgery performed on 3/8/23. 4. In the MOHS logbook and on the patient slides showed that Patient "C" MOHS case identification number was C23-34. 5. Patient "C" MOHS map from 3/8/23 showed that the case was performed at "5530 Wisconsin AVE, Chevy Chase Maryland and the case number was C23-34. 6. Patient "C" final report from 3/8/23 showed the MOHS identification number was 23-34. 7. The MOHS tech stated that the letter "C" infront of the numbers was for the first letter of the MOHS surgeon last name performing testing that day. 8. The MOHS tech confirmed on 9/6/24 at 1:00 PM by phone call that the lab director failed to identify and correct problems during the post assessment process.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of patient final reports, Quarterly Slide and Case Review, and interview with lab staff, the lab director failed to ensure that all corrective action procedures were performed when the laboratory failed to meet the criteria of

	acceptability when performing MOHS testing. Findings: Refer to D5805 and D5891 The lab director failed to ensure that remedial action procedures were identified and documented when lab testing deviated from acceptable performance characteristics.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the technical supervisor failed to ensure that quality assessment procedures were performed during MOHS surgical procedures. Finding: Refer to D5791 1. The laboratory tests for skin carcinoma from tissue samples obtained during MOHS surgery. 2. Review of the MOHS patient log, patient maps, and case slides on 11/30/23 showed that one out of three patients MOHS case identification number did not match throughout the analytic process. 3. Patient "A" perfromed on 11/30/23 case number on the MOHS log was C23-124, on the patient map the case number was 23-124, and on the case slides the number was 23-124. 4. The MOHS tech stated that the letter "C" in front of the numbers was for the first letter of the MOHS surgeon last name performing testing that day. 5. The MOHS tech confirmed on 9/6/24 at 1:00 PM by phone call that the technical supervisor did not maintain quality assessment procedures when performing MOHS surgery.