Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0666655	01/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Integrated Dermatology Of Calumet City, L L C	19 River Oaks Drive, Calumet City, 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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on review of patient testing logs and patients' test reports for the time period of December 21, 2016 to November 1, 2017 and interview, it was determined the testing personnel failed to retain histopathology slides for at least 10 years from the date of examination. Findings: 1. During survey date 01/22/18 at 11:00 AM, the surveyor selected a total of 4 patients test records for review. The review included the following information: a. Patients' test reports b. Patients' test records c. Slide review 2. Histopathology slides were not retained by the laboratory. There were no patients' slides available for review. 3. During survey date 01/22/18 at 12:30 PM, the medical assistant confirmed the surveyor's findings.
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by:

	Based on review of laboratory procedures and patients' test records the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299. Findings: 1. The laboratory failed to verify its histopathology procedures. See D5217 2. The laboratory failed to monitor and evaluate the overall quality of the analytic systems for its histopathology procedures. See D5400.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on observation; review of the laboratory's procedures manual and patients' test records; and interview, laboratory personnel failed to verify the accuracy of its histopathology staining procedures at least twice annually: Findings: 1. Director observation revealed that the laboratory performed KOH and Histopathology (MOHs) staining procedures. 2. There were no instructions that described the laboratory's process for verifying its Histopathology procedures. 3. Review of laboratory patients' test records revealed that the laboratory began performing Histopathology testing in December 2016. However, there was no documentation to show that the laboratory performed verification of its' Histopathology staining procedures in at least twice in 2017. 4. During survey date 01/22/18 at 12:30 PM, the medial assistant confirmed the surveyor's findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the surveyors' reviews of the laboratory's procedures manual and records, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing for Histopathology (Mohs) testing using Hematoxylin and Eosin (H&E) stains. Findings: 1. The laboratory failed to have a written comprehensive procedures manual for all tests that the laboratory performs. See D5401. 2. The laboratory failed to establish and perform maintenance or preventative maintenance of its laboratory equipment. See D5433 3. The laboratory failed to perform and document quality control of its H&E staining procedures. See D5473 4. Histopathology reports were not signed by a qualified individual. See D5607 5. Histopathology test reports lacked required information when reporting patients' final test results. See D5805
D5401	PROCEDURE MANUAL

	CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation, review, and interview, a written procedures manual for all tests, assays, and examinations performed by the laboratory was not available, and followed by laboratory personnel. Findings: 1. During the walk-through of the laboratory on January 22, 2018 at 10:00 AM, the surveyor observed the following equipment in the laboratory: Microscope; Microtome; Stains; Log Sheets for Frozen Section Surgery; and a KOH procedures manual. 2. Review of 4 patients' test records revealed that there was a Mohs surgical report generated for 4 of 4 patients' test records reviewed. However, there was no documentation to show that there are procedures for Histopathology Mohs testing. 3. During survey date 01/22/18 at 12:30 PM, the medical assistant confirmed the surveyor's findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observation, review, and interview, the laboratory failed to establish, a maintenance protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test result reporting. Findings: 1. During survey date 01/22/18, the surveyor observed that the laboratory performed KOH and Mohs Histopathology procedures. 2. Review of the laboratory procedures manual revealed that there were no procedures that described how laboratory equipment (microtome and microscope) were maintained. Also, there was no documentation to show that maintenance and/or preventative maintenance of Mohs laboratory equipment was performed. 3. During survey date 01/22/18 at 12:30 PM, the medical assistant confirmed the surveyor's findings.
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 patients test records and interview, the laboratory failed to test and document staining materials for intended reactivity each day it tested patients' specimens. Findings: 1. During survey date 01/22/18 at 11:00 AM, the surveyor requested the following information for 4 patients' selected from testing logs: a. The printed patients' test reports. b. Documentation of Quality Control (QC)of the Hematoxylin and Eosin (H&E) staining procedures. 2. There was no documentation to show that QC of the H&E stain was performed each day patients' test were performed for 4 of 4 days for 4 of 4 patients' test records reviewed from December 21, 2016 to November 1, 2017. 3. During survey date 01/22/18 at 12:30 PM, the medical assistant confirmed the surveyor's findings.
D5607	HISTOPATHOLOGY CFR(s): 493.1273(d)(f) (d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. (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 patients' test reports and interview, Tissue pathology reports were not signed by a qualified individual. Findings: 1. Review of 4 patients' test reports revealed that the laboratory has an electronic medical record (EMR) for documenting patients' test results. Further review of patients' test reports revealed that the Mohs surgeon did not sign the final report of 4 of 4 patients test reports reviewed. 2. During survey date 01/22/18 at 12:30 PM, the medical assistant 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 review of patients' test reports and interview, the test report failed to indicate the following: *The name and address of the laboratory location where the test was performed. Findings: 1. Review of 4 patients' test reports revealed that the name and address location where the test was performed was not documented on the final report of 4 of 4 patients' test reports reviewed. 2. During survey date 01/22/18 at 12:30 PM, the medial assistant confirmed the surveyor's findings.

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 laboratory tests and personnel records, the laboratory did not have a laboratory 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. Finding: 1. The current laboratory director lacks the appropriate credentials that show he qualifies to direct personnel and manage high complexity tests. See D6078.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by:

	Based on observation, review, and interview, the laboratory director failed to be qualified to manage and director the laboratory personnel and performance of high complexity tests as specified at 493.1443. Findings: 1. During survey date 01/22/18 the surveyor observed that the laboratory has laboratory equipment for performing histopathology procedures. 2. Review of patients testing logs revealed that there is documentation to show that the laboratory performed cutting and staining of frozen histology specimens. 3. Review of personnel records revealed that the current laboratory director did not have the necessary credentials to show that he is eligible to operate and manage laboratory personnel and performance of high complexity tests. 4. On 01/24/18 at 1:45 PM in a telephone interview, the laboratory director confirmed the surveyor's findings.