Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2107105	08/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Indigo Dermatology Llc	675 S Babcock St, Melbourne, FL	

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
D0000	A recertification survey was conducted on August 5, 2020. Indigo Dermatology LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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 record review and interview, the laboratory's Quality Assessment Program failed to monitor and evaluate the overall quality of the analytic system and correct identified problems. Cross Reference D5403: Based on observation, record review and interview, the laboratory procedure manual failed to include the instructions for making the 95% reagent grade alcohol in their H&E (Hematoxylin and Eosin) stain. Cross Reference D5601: Based on record review and interview, the laboratory failed to have negative control slides for recording the negative reactivity for each Immunohistochemical (IHC) stains from 8/5/18 to 8/5/20. Cross Reference D5609: Based on record review and interview, the laboratory failed to document the lot number, expiration date and open dates for reagents used in their Hematoxylin & Eosin (H & E) stains from 7/8/18 to 8/5/20 (July 2018 - March 2019, May 2019 - August 2019, November 2019 - February 2020, July 2020 - August 2020) for 19 out of 26 months (July 2018 - August 2020). This is a repeat deficiency from the survey performed on 6/19/18.

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, record review and interview, the laboratory procedure manual failed to include the instructions for making the 95% reagent grade alcohol in their H&E (Hematoxylin and Eosin) stain. Findings: During a tour of the laboratory on 8/5 /20 at 10:55 AM, there was only 100% reagent grade alcohol in the cabinet containing flammable liquids. Review of the procedure titled "Mohs Procedure" showed the procedure failed to include instructions for making the 95% reagent grade alcohol. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 8/5/20, the laboratory had an estimated annual test volume of 2000 test per year. During an interview on 8/5 /20 at 1:14 PM, the Laboratory Consultant stated there were not any instructions for making the 95% alcohol, and that the Mohs Tech told him that they make up the 95% alcohol in their H&E stain.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have negative control slides for recording the negative reactivity for each Immunohistochemical (IHC) stains from 8/5/18 to 8/5/20. Findings: Review of slides for patients with biopsies performed showed that there was no negative control slides for 4 out of 4 (#1, 2, 3, 4) patient slides reviewed. The laboratory evaluated the following IHC stains: CD34

	(Cluster of Differentiation 34 progenitor cells IHC stain), EMA (Epithelial Membrane Antigen IHC stain), Ep-CAM (BerEp4) (Epithelial Antigen IHC stain), Factor XIIIa (Factor XIIIa protein IHC stain), Ki-67 (Nuclear Non-histone Protein IHC stain), MART-1/Melan-A (Melanocytic Marker IHC stain), MITF (Microphthalamia Transcription Factor IHC stain), S-100 (Neural Tissue/Lesion and Melanoma IHC stain), and SMA (Smooth Muscle Actin IHC stain). During an interview on 8/5/20 at 1:39 PM, the Laboratory Consultant stated they did not have separate negative control slides for IHC stained slides.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the lot number, expiration date and open dates for reagents used in their Hematoxylin & Eosin (H & E) stains from 7/8/18 to 8/5/20 (July 2018 - March 2019, May 2019 - August 2019, November 2019 - February 2020, July 2020 - August 2020) 19 out of 26 months (July 2018 - August 2020). This is a repeat deficiency form the survey performed on 6/19/18. Findings: Review of the laboratory's Plan of Correction (POC) from the survey performed on 6/19/18 showed that "the director redid the slide log to show both the expiration and lot number on the log. The date given as to when the deficient practice was corrected for the survey performed on 6/19/18 was 7/8/18. Record review of the Reagent Control Sheet showed that only seven monthly logs were available for review (April 2019, September 2019, October 2019, March 2020, April 2020, May 2020 and June 2020). No other reagent logs were available for review. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 8/5/20, the laboratory had an estimated annual test volume of 2000 tests per year. During an interview on 8/5/20 at 1:05 PM, the Laboratory Consultant stated he did not know where the reagent log was located.
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 record review and interview, the Laboratory Director failed to provide overall management and direction. Cross Reference D6082: Based on record review and interview, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including analytic phases of testing from 7/8/118 to 8/5/20.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)

	The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including analytic phases of testing from 7/8/118 to 8/5/20. Findings: The Laboratory Director failed to ensure that the laboratory procedure manual included the instructions for making the 95% reagent grade alcohol in their H&E (Hematoxylin and Eosin) stain. (See D5403) The Laboratory Director failed to ensure that, the laboratory had negative control slides for recording the negative reactivity for each for Immunohistochemical (IHC) stains from 8/5/18 to 8/5/20. (See D5601) The Laboratory Director failed to ensure that the laboratory documented the lot number, expiration date and opened dates for reagents used in their Hematoxylin & Eosin (H & E) stains from 7/8/18 to 8/5/20 for 19 (July 2018 - March 2019, May 2019 - August 2019, November 2019 - February 2020, July 2020 - August 2020) out of 26 months (July 2018 - August 2020). This is a repeat deficiency from the survey performed on 6/19/18. (See D5601)