Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2268476	12/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Indigo Dermatology Llc	14499 N Dale Mabry Hwy Ste 129-S, Tampa, 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	An announced CLIA recertification survey was conducted at Indigo Dermatology LLC on 11/18/2024 through 12/3/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6076 - 42 C.F.R. 493.1441: Laboratories performing high complexity testing; laboratory director; D6168 - 42 C.F.R. 493.1487: Laboratories performing high complexity testing; testing personnel;
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory failed to monitor the laboratory room temperature and humidity as required by the manufacturer's instructions for one of one cryostat for two of two years (2023 and 2024). Findings included: A tour of the laboratory on 11/18/2024 at 10:15 AM revealed the lab had a Tissue-Tek Cryostat in operation. Review of the manufacturer instruction's/manual, dated 02/24/2006, showed operating environmental requirements included: 15 degrees to +35 degrees Celsius, and relative humidity of 15% to 85%, non-condensing. Interview with Testing Person C on 11/18/2024 at 12:30 PM confirmed the lab does not monitor the temperature or humidity.
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 interview and record review, the laboratory failed to document quality control (QC) slides were prepared and evaluated for two of two years (2023 and 2024). Findings included: Review of the QC slide log, provided on 11/18/2024, showed no documentation testing personnel performing slide interpretation evaluated the quality control slides or documented the quality control slides were prepared since the initial certification survey ending 3/30/2023 through the last entry made on the log of 8/29/24. Electronic correspondence with the Laboratory Directory on 11/26/24 revealed the doctor visually assessed the quality control slide which was documented on the quality control log. This documentation was not present on the QC slide log provided by Testing Person C while on-site at the laboratory on 11/18/24.
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: The Lab Director failed to provide overall management and oversight of the lab for two of two years (2023 and 2024). The Lab Director failed to maintain an effective quality assurance program that identified failures or problems for the lab that included: (1) failure to identify and dispose of expired reagents, (2) failure to document quality control slides were created and acceptable, (3) failure to complete monthly quality assurance reviews per the laboratories policy, (4) failed to identify a testing person performing grossing failed to meet the qualifications, (5) failed to identify a fume hood or respirator was required to protect employees from chemical hazard, (6) failed to identify the policy and procedure manual did not contain job descriptions for clinical consultant, technical supervisor and general supervisor, and (7) failed to identify room temperature and humidity must be monitored per manufacturer instructions for the operation of a cryostat. (See D6094, D6168, D6171).
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory director failed to

	ensure appropriate equipment was available to protect employees from chemical hazards for two of two years (2023 and 2024). Findings included: A tour on 11/18/24 at 10:15 AM revealed a manual staining station with no fume hood was present. A bottle of CoverMount, Xylene, with a flammable pictogram on the label, was sitting on the counter top at the manual staining station. Interview with Testing Person C, at the time of observation, confirmed a fume hood was not used when using the flammable product. Testing Person C reported working at the lab since 2023 with no fume hood in use. Review of the Safety Data Sheet for CoverMount, Xylene revealed the product should be locked up when stored and used in a well ventilated area to prevent exposure, do not breathe vapors, and if a ventilation hood is not available wear a respirator. No respirators were present in the laboratory. Photographic evidence was obtained.
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: Based on observations, interview and record review the laboratory director (LD) failed to maintain an effective quality assessment program to identify failures or problems for two of two years (2023 and 2024). Findings included: Review of the Policy and Procedure manual, signed by the LD 01/09/2023 and 01/10/24, revealed a three page Quality Assurance Program policy, dated 01/11/18 was in place. Review of page 2 showed the LD would review quality control charts and logs on at least a monthly basis. On 11/18/2024 at 1:30 PM, Testing Person C confirmed there were no Quality Assurance Monthly reviews performed since 2023. On 11/20/24 and 11/26/24 the LD sent Monthly Quality Assurance checklists through electronic correspondence. Review of the Quality Assurance checklists submitted revealed it was not completed for the months of 01/2024, 02/2024, 06/2024, 07/2024 or 10/2024. Quality assurance checklists for 04/2023 through 12/2023, 03/2024, 04/2024, 08/29/2024 showed: All reagents that exceeded expiration date were discarded. A tour of the lab on 11/18 /2024 at 10:15 AM revealed two expired, opened reagents were in the flammable storage cabinet: Eosin /Alcoholic 0.25% with an expiration date of 04/30/2024 and 100% Reagent Alcohol with an expiration date of 03/31/2024. Testing Person C confirmed the reagents were expired at the time of the tour. Hematoxylin and Eosin stain quality controls performed and documented within normal limits before test results reported. Review of Quality Control slide logs for 2023 and 2024 revealed no documentation Quality Control was documented as performed or acceptable (see D5473). The Quality Assessment program failed to identify an unqualified Testing Person (C) was performing grossing (see D6171). The Quality Assessment program failed to identify a fume hood or respirator was required to protect employees from chemical hazards (see D6084). The Quality Assessment program failed to identify there were no Job Descriptions in the policy and procedure manual for the clinical consultant, technical supervisor and general supervisor. This was confirmed via email by the lab director on 11/26/2024. The Quality Assessment program failed to identify the laboratory room temperature and humidity must be monitored as required by the manufacturer's instructions for one of one cryostat (see D5413).
D6168	TESTING PERSONNEL

	CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on interview and record review, the laboratory failed to ensure one (Testing Person C) of three Testing Personnel (A-C) was qualified to perform high complexity testing for Histopathology (see D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent

	stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on interview and record review, the laboratory failed to ensure one (Testing Person C) of three Testing Personnel (A-C) was qualified to perform the high complexity testing of grossing for Histopathology for two of two years (2023 and 2024). Finding included: Electronic correspondence with the Lab Director on 11/26/24 revealed Testing Person C performed grossing for Histopathology testing. Review of Testing Person C's competency assessments dated 7/13/2023, 1/15/2024, and 07/16/2024, signed by the Lab Director revealed Testing Person C was assessed for "proper grossing techniques utilized", "recognizes type of tissue for gross identification", and "recognizes abnormal finding in gross specimens". All assessments reflected "yes". Review of Testing Person C's personnel documentation revealed the highest level of education completed was a high school diploma.