Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2120643	09/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Integrated Dermatology Of Ponchatoula, Llc	180 N 5th Street, Ponchatoula, LA	

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 performed at Integrated Dermatology of Ponchatoula, LLC, CLIA ID 19D2120643, on September 27, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 by surveyor, review of the laboratory's policies, temperature logs, manufacturer's storage requirements, and interview with personnel, the laboratory failed to define the humidity limit for area where the cryostat is stored. Findings: 1. Observation by the surveyor during the laboratory tour revealed the laboratory utilized the Leica CM 1510 S cryostat. 2. Review of the Leica CM 1510 S Cryostat manual revealed the acceptable humidity was defined as less than or equal to 60%. 3. Review of the laboratory's policies and temperature logs revealed the laboratory did not define the acceptable humidity limit. 4. In interview on September 27, 2024 at 10:50 am, the Medical Assistant confirmed the laboratory did not define the acceptable humidity limit for the room where the cryostat is stored.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the laboratory failed to ensure laboratory reagents and supplies had not exceeded their expiration date for Histopathology testing. Findings: 1. Observation by surveyor during the laboratory tour on September 27, 2024 at 9:37 am revealed the following expired items: a) Cancer Diagnostics CDI's Tissue Marking Black Dye, Lot 22075, Expiration Date: 2024-03-31, Quantity: one (1) bottle b) Cancer Diagnostics CDI's Tissue Marking Orange Dye, Lot 22056, Expiration Date: 2024-02-28, Quantity: one (1) bottle c) Cancer Diagnostics CDI's Tissue Marking Violet Dye, Lot 22033, Expiration Date: 2024-02-28, Quantity: one (1) bottle d) Platinum Line Microtome Oil, Lot 111649, Expiration Date: 2022-12-31, Quantity: one (1) bottle e) Scott's Tap Water Substitute, Lot 2310024, Expiration Date: 2024-04-20, Quantity: one fourth (1/4) of one (1) gallon 2. In interview on September 27, 2024 at 9:48 am, the Medical Assistant confirmed the identified items were expired.
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 review of the laboratory's CMS-209 form, review of policies, quality control records, and interview with personnel, the laboratory failed to ensure Testing Personnel documented the stain quality for Hematoxylin and Eosin (H&E) stains for four (4) of eight (8) random selection of cases reviewed. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Laboratory Director and Testing Personnel 1 served as Testing Personnel. 2. Review of the laboratory's "Quality Assurance" policy under the "Monitor of Quality Control Testing" revealed "The first slides of the day will be reviewed for staining quality. The testing Physician will review the slides for quality." 3. Review of the laboratory's quality control logs and random selection of patients revealed the quality control slides were not assessed by Testing Personnel 1 on the following test dates: September 15, 2023: P23 056 November 10, 2023: P23 071 March 15, 2024: P24 020 August 23, 2024: P24 040 4. In interview on September 27, 2024 at 10:50 am, the Medical Assistant confirmed Testing Personnel 1 did not document his assessment of the stain quality for his cases for the identified dates.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

	This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to define the humidity limit for area where the cryostat is stored. Refer to D5413. 2. The laboratory failed to ensure laboratory reagents and supplies had not exceeded their expiration date for Histopathology testing. Refer to D5417.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D5609.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the 2023 annual competency assessment was performed for one (1) of two (2) testing personnel performing high complexity testing. Refer to D6128.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, personnel records, and interview with personnel, the Technical Supervisor failed to perform competency assessments annually in 2023 for one (1) of two (2) testing personnel reviewed. Findings: 1. Review of the laboratory's policies revealed "Competency Evaluations: Yearly evaluations will be conducted on all laboratory personnel. These evaluations will be

	maintained in the Laboratory Manual." 2. Review of personnel records revealed the 2023 competency assessment for Testing Personnel 1 was not completed. 3. In interview on September 27, 2024 at 10:07 am, the Medical Assistant confirmed the 2023 annual competency was not completed for Testing Personnel 1.