Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2299994	09/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Integrated Dermatology Of Northshore	201 Hewitt Road, Suite A, Hammond, 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	An Initial survey was performed at Integrated Dermatology of Northshore, CLIA ID 19D2299994, on September 25, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following policies: a) Complaint Investigations to include how to address, document, and handle complaints or problems reported to the laboratory b) Twice a year verification for the accuracy of Histopathology testing, to include, but not limited to frequency of performance and corrective action for discrepancies. 2. In interview on September 25, 2024 at 1:41 pm, the Laboratory Director confirmed the laboratory did not have a written policy for twice a year verification of Histopathology testing. 3. In interview on September 25, 2024 at 2:50 pm, the Office Manager confirmed the laboratory did not have a written policy for complaints.
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 review of the laboratory's policies, records, and interview with personnel, the laboratory failed to perform microscope preventative maintenance per laboratory policy for five (5) of five (5) months in 2024. Findings: 1. Review of the laboratory's policy revealed "Routine maintenance of the microscope is very important and should be a part of the routine quality maintenance program. The microscope will be cared for as outlined": a) "Keep the microscope covered when not in use" b) "Clean the lens frequently with lens paper. Do not use other tissue paper." c) "Remove immersion oil immediately after use" d) "Use Xylene on the objectives only as a last resort. Use it sparingly and remove it immediately" e) "Do not dismantle objectives" f) "Be careful, when using immersion oil, that the high-powered dry lens is not dragged through the oil" g) "Reduce the light to a minimum, or turn it off, when microscope is not in use" 2. Review of the laboratory's records revealed the laboratory did not document performance of microscope maintenance since opening the location in April 2024. 3. In interview on September 25, 2024 at 1:41 pm, the Laboratory Director confirmed she did not document the microscope maintenance.
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 policies, patient test logs, 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 one (1) of eight (8) random selection of dates reviewed. Findings: 1. Review of the laboratory's "Quality Assurance" policy under the "Monitor of Quality Control Testing" section revealed "The first slides of the day will be reviewed for staining quality. The testing Physician will review the slides for quality. The date and case number of each quality control slide will be documented on the Hematoxylin and Eosin Quality Control Sheet." 2. Review of random selection of patient test logs and stain quality control records revealed the Laboratory Director, who serves as Testing Personnel, did not document the stain quality for testing performed on September 4, 2024. 3. Further review of the patient test logs revealed the following two patients were reported without documentation of the stain quality: AC24-10753 AC24-10754 4. In interview on September 25, 2024 at 2:00 pm, the Laboratory Director stated the date slides are received is used as the quality control date. The Laboratory Director confirmed the stain quality was not documented for September 4, 2024.
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 review of records and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to perform microscope preventative maintenance per laboratory policy for five (5) of five (5) months in 2024. Refer to D5433. 3. The laboratory failed to ensure testing personnel documented the stain quality for Hematoxylin and Eosin (H&E) stains for one (1) of eight (8) random selection of dates reviewed. Refer D5609.
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.
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 record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5791.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, records, and interview with personnel,

	the Laboratory Director failed to ensure maintenance procedures were followed to ensure acceptable levels of test performance. Refer to D5433.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.