Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 19D0918803	**(X3) Date Survey Completed** 12/08/2022
Name of Provider or Supplier Louisiana Dermatology Associates	**Street Address, City, State** 10154 Jefferson Highway, Baton Rouge, 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 Certification survey was performed on December 8, 2022 at Louisiana Dermatology Associates, CLIA ID # 19D0918803. 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 review of the laboratory's policies, temperature logs, and interview with personnel the laboratory failed to define the acceptable temperature ranges for the paraffin dispenser and room temperature. Findings: 1. Review of the laboratory's "Instrument and Equipment Maintenance and Schedules/List" policy revealed the following: a) Paraffin Dispenser: "The temperature is kept from 56-63 degrees." 2. Review of the laboratory's "Temperature and Humidity Monitoring for Histology" policy revealed "Laboratory temperature: range 50-75 degrees F." 3. Review of the laboratory's "Quality Control in Histology" policy revealed the following acceptable ranges which differed from the other two (2) policies: a) "The technician will check room temperature and humidity each work day and record on the Temperature /humidity Maintenance Log. Acceptable range is 55-77 F." b) "The technician will check and log paraffin temp of paraffin dispenser range is 55-63 C" 4. Review of the laboratory's temperature logs revealed the following acceptable temperature ranges

	which differed from the policies: a) "Paraffin Temp 55-63 C" b) "Temp Range 60 -77 F" 5. In interview on December 8, 2022 at 10:21 am, the Testing Personnel confirmed the acceptable temperature ranges in the policies did not match those on the temperature logs.
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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5413.
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 policies and procedures for assessing personnel competency were maintained. 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 competency assessment records and interview with personnel, the Technical Supervisor failed to perform competency annually in 2021 for one (1) of one (1) testing personnel reviewed. Findings: 1. Review of the laboratory's "Competency Assessment Record-Histotech" form revealed assessments are performed as an initial training, semi-annually, annually, and reassessment if needed. 2. Review of the competency assessment records for the Testing Personnel revealed the laboratory did not have documentation of an assessment in 2021. 3. In interview on December 8, 2022 at 10:30 am, the Testing Personnel stated competency assessment are done in December each year. The Testing Personnel further stated his 2021 competency was performed on January 8, 2022 because he was on vacation

	during December of 2021. The Testing Personnel stated the laboratory would perform another competency assessment in December 2022 to count as the 2022 annual assessment. 4. Further review of the competency assessment records for the Testing Personnel revealed the year indicated was "2022" and did not include documentation of acknowledgment of delay in 2021. 5. In further interview on December 8, 2022 at 10:30 am, the Testing Personnel and National Director of Laboratory Operations confirmed the laboratory did not have documentation of a 2021 competency assessment for the Testing Personnel. The Testing Personnel and National Director of Laboratory Operations further confirmed the laboratory did not have documentation of the delay or laboratory's plan of performance of an additional assessment in 2022.