Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2308152	01/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Clinic - Lake Charles I	1800 Barbe St, Lake Charles, 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 certification survey was conducted January 14, 2025 at Dermatology Clinic - Lake Charles I - CLIA ID # 19D2308152. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policies and personnel records as well as interview with personnel, the laboratory failed to follow their competency assessment policy for one (1) of one (1) personnel serving as General Supervisor. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed one (1) testing personnel serving as General Supervisor. 2. Review of the laboratory's policy "Competency" section 5.4 revealed "Competency must be assessed for Technical Supervisor, General Supervisor, Technical Consultant and Clinical Consultant as well for all delegated duties at least annually...." 3. Review of personnel records revealed a competency assessment for the personnel serving as General Supervisor was not performed. 4. In interview on January 14, 2025 at 1:14 p.m., the Testing Personnel confirmed a competency for his role as General Supervisor was not performed.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) (c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing

	program. This STANDARD is not met as evidenced by: Based on review of laboratory policies and proficiency testing records, the laboratory failed to document all steps performed for alternative assessment of Histopathology testing for one (1) of one (1) event reviewed. Findings: 1. Review of laboratory policy "Proficiency Testing" section 5.4 revealed the following instructions for proficiency testing alternate performance assessment: - "For those analytes/tests where commercially available proficiency testing material are not options, perform alternative performance assessment twice per calendar year." - "Select patient samples OR verified standards or control material at know concentrations that contain the specific analytes to be split and submitted to a single CLIA-certified reference laboratory for comparative testing, or comparison to appropriate peer group of CLIA-certified laboratories, if available." 2. Further review of the policy "Proficiency Testing" revealed the laboratory did not include the following: a) The number of cases /patients to be reviewed b) The name of the CLIA certified laboratory performing the comparison 3. Review of proficiency testing records for July 2024 revealed the name and address of a sister facility and did not include documentation of the location where the original slides were tested.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's polices and proficiency testing records as well as interview with personnel, the laboratory failed to perform an assessment of performance for one (1) of one (1) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's policy "Proficiency Testing" section 5.4.11 revealed "Evaluation - Review of the results, signed by the Laboratory Director and Testing Personnel." 2. Review of the proficiency testing event for July 2024 revealed no assessment of performance by laboratory personnel to include the Laboratory Director and/or testing personnel. 3. In interview on January 14, 2025 at 2:13 p.m., the Testing Personnel confirmed the laboratory did not have documentation of review by the Laboratory Director and/or Testing Personnel.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with laboratory personnel, the laboratory failed to ensure laboratory policies and procedures were approved and signed by the laboratory director. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory director did

	not sign the policies and procedures in use. 2. In interview on January 14, 2025 at 2: 15 p.m., the Testing Personnel confirmed the laboratory director did not sign the laboratory's policies and procedures.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Refer to D5219.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D5221.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form, policies, and personnel records; as well as interview with personnel, the Laboratory Director failed to ensure one (1) of one (1) Testing Personnel had documentation of training prior to patient testing. Findings: 1. In interview on January 14, 2025 at 9:15 am, the General Supervisor confirmed Histopathology patient testing began July 22, 2024. 2. Review of the

	laboratory's CMS-209 form (Laboratory Personnel Report) revealed the laboratory had one (1) Testing Personnel. 3. Review of the laboratory's policy "Competency" section 5.2 revealed "Competency is evaluated during on-the-job training, proficiency testing, and randomly during the technical audits of test methods. Competency is assessed and documented prior to initiating testing, at six months during the first year of employment, at one year of employment and annually thereafter...Prior to starting patient testing and reporting patient results for new methods or instruments, each individual must have training and be evaluated for proper test performance." 4. Review of personnel records revealed the Testing Personnel did not have documentation of training for Histopathology testing. 5. In interview on January 14, 2025 at 2:05 p.m., the General Supervisor stated training was performed, but he did not know if it was documented. He confirmed the laboratory did not have documentation of training.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) 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 review of policies, personnel records, and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and 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 D5407.