Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0456688	11/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Family Dermatology Specialists, Llc	3421 N Causeway Boulevard Suite 202, Metairie, 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 Family Dermatology Specialists, LLC, CLIA ID 19D0456688, on November 21, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements 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: I. Based on review of the laboratory's policies, competency records, and interview with personnel, the laboratory failed to follow their established competency assessment policy for one (1) of one (1) testing personnel for 2023. Findings: 1. Review of the laboratory's competency policy revealed the "Director of the laboratory will assess the laboratory personnel annually by completing the competency form located in the form section of this manual." 2. Review of the laboratory's "Personnel Assessment" form revealed "CLIA guidelines require the semiannual assessment of personnel competency during the first year of test performance for Moderate or High Complexity testing. Thereafter, evaluation must be performed at least annually." The "Personnel Assessment" form included the six (6) monitors required. 3. Further review of the "Personnel Assessment" form for the Testing Personnel revealed the Laboratory Director did not perform an annual assessment in 2023. 4. In interview on November 21, 2024 at 11:06 am, the Medical Assistant confirmed the Laboratory Director did not perform the 2023 annual competency assessment for the Testing Personnel. II. Based on review of the laboratory's CMS-209 form, policies, competency records, and interview with personnel, the laboratory failed to follow

	their established competency assessment policy for one (1) of one (1) personnel serving as Clinical Consultant, Technical Supervisor, and General Supervisor for 2023. Findings: 1. Review of the laboratory's competency policy revealed the "Director of the laboratory will assess the laboratory personnel annually by completing the competency form located in the form section of this manual." 2. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the Testing Personnel also served as the Clinical Consultant, Technical Supervisor, and General Supervisor. 3. Review of the laboratory's competency records revealed a delegation of duties letter dated "October 15, 2018" that stated "This will be reviewed by the Lab Director at six months and twelve months the first year, then annually thereafter for accuracy and completeness." 4. Review of the "Annual Assessment of Delegations (CC, GS, TS)" for the Testing Personnel revealed the following tasks: "Reviewed QC Data, Proficiency testing performed and test methodology, QA program monitored for compliance, Monitored proficiency testing, Monitored patient management system, Testing personnel assessments reviewed and signed for lab personnel, If applicable, notify laboratory director of any situation that could affect laboratory's performance or safety of employees." 5. Further review of the "Annual Assessment of Delegations (CC, GS, TS)" revealed the Laboratory Director did not perform an assessment in 2023 for the Testing Personnel's duties as Clinical Consultant, Technical Supervisor, and General Supervisor. 6. In interview on November 21, 2024 at 11:06 am, the Medical Assistant confirmed the Laboratory Director did not perform the 2023 annual competency assessment for the Testing Personnel's duties as Clinical Consultant, Technical Supervisor, and General Supervisor.
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 policies and interview with personnel, the laboratory failed to have a complete policy for twice a year verification for Histopathology testing. Findings: 1. Review of the laboratory's policies under the "Proficiency Testing/Quality Assessment Program" section revealed "Proficiency by a consulting dermatopathologist or another Mohs surgeon will be done twice a year. This form is for evaluation of diagnostic abilities of the Mohs surgeon and the quality of the slides produced by the histotechnologist." 2. Further review of the "Proficiency Testing/Quality Assessment" policy revealed the laboratory failed to include corrective actions for result discrepancies. 3. In interview on November 21, 2024 at 11:04 am, the Medical Assistant confirmed the written policy did not include actions to take if there is a discrepancy in the results.
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, maintenance records, and interview with personnel, the laboratory failed to perform cryostat maintenance per policy for eighteen (18) of eighteen (18) days in 2024. Findings: 1. Review of the laboratory's policies under the "Cryostat Care" section revealed the following: "All other loose and removable items are to be removed from the cryostat and placed on a towel on the counter to be wiped with 70% alcohol or washed with soap and water. Using brushes, remove as much loose OCT/tissue debris as possible. With a gauze saturated with 70% ethanol, wipe all interior surfaces that can be reached. Use clean gauze as needed. Wipe with dry gauze. Wipe glass, fly wheel and outside of cryostat with 70% alcohol Change paper towels and other top items as needed." 2. Review of the laboratory's 2024 "Cryostat Maintenance Record" revealed the following maintenance tasks: "Clean interior, Thermometer Check, Moving Components, Clean Air Filter, Preventative Maintenance, Defrost Machine." 3. Further review the laboratory's 2024 "Cryostat Maintenance Record" revealed the laboratory did not have documented performance of the following tasks:"clean interior, moving components, clean air filter, defrost machine," for the identified in-use dates: January 9, 2024 January 30, 2024 February 20, 2024 March 12, 2024 March 26, 2024 April 9, 2024 April 30, 2024 May 21, 2024 June 4, 2024 June 25, 2024 July 16, 2024 July 23, 2024 August 6, 2024 August 27, 2024 September 17, 2024 October 8, 2024 October 29, 2024 November 12, 2024 4. In interview on November 21, 2024 at 11:00 am the Medical Assistant confirmed the laboratory did not document the performance of the cryostat maintenance for the identified dates in 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 the laboratory's quality assessment records, maintenance records, and interview with personnel, the laboratory failed to establish complete procedures to identify issues within the analytic system. Findings: 1. Review of the laboratory's "Monthly Patient Quality Assurance Checklist" revealed the laboratory selects one (1) random case each month to check the following: "Specimens were logged correctly, Quality Control policies were performed, and slides reviewed including map and slides properly reported by surgeon." 2. Further review of the laboratory's "Monthly Patient Quality Assurance Checklist" revealed the monitors did not identify the following failures within the analytic system: a) The laboratory failed to have a complete policy for twice a year verification for Histopathology testing. Refer to D5401. b) The laboratory failed to perform cryostat maintenance per policy for

	eighteen (18) of eighteen (18) days in 2024. Refer to D5433. 3. In interview on November 21, 2024 at 11:00 am, the Medical Assistant confirmed the laboratory's quality assurance monitors were not complete.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the laboratory's CLIA certificate, patient operative reports, and interview with personnel, the laboratory failed to utilize the correct CLIA identification number of the testing laboratory for seven (7) of eight (8) patient reports reviewed. Findings: 1. Review of the laboratory's CLIA certificate revealed the CLIA identification number as 19D0456688. 2. Review of random selection of patient operative reports (final test reports) revealed the laboratory provided a CLIA identification number of another facility, 19D2120244, for the following patients: January 24, 2023: Patient M23-013 April 18, 2023: Patient M23-071 December 7, 2023: Patient M23-234 February 20, 2024: Patient M24-028 May 21, 2024: Patient M24-085 July 23, 2024: Patient M24-135 October 29, 2024: M24-195 3. In interview on November 21, 2024 at 10:54 am, the Medical Assistant confirmed the testing was performed at their location and the CLIA identification number listed on the patient reports was incorrect. The Medical Assistant stated the wrong template was used for the patient reports.
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 established 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, maintenance 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.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.
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 D5209 I and D5209 II.
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.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to have a complete policy for twice a year verification for Histopathology testing. Refer to D5401. 2. The laboratory failed to perform cryostat maintenance per policy for eighteen (18) of eighteen (18) days in 2024. Refer to D5433. 3. The laboratory failed to utilize the correct CLIA identification number of the the testing laboratory for seven (7) of eight (8) patient reports reviewed. Refer to D5805.