Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D0891635	**(X3) Date Survey Completed** 09/15/2022
Name of Provider or Supplier Dermatology Specialists Of Georgia , Llc	**Street Address, City, State** 1605 Whitesville Street, Lagrange, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on September 15, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on Proficiency Testing (PT) document review and staff interview, the laboratory failed to enroll and participate in PT for all regulated tests or procedures performed. Findings include: 1. PT document review revealed there were no PT performed for Parasitology testing in 2021 and 2022 thus far. 2. An interview with the laboratory director (CMS 209) and the clinical coordinator in the facility's breakroom on 9/15/2022 at approximately 11:50 a.m. confirmed the lack of Parasitology PT for the aforementioned dates.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations

	Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) document review and staff interview, the laboratory failed to perform and document QC on potassium hydroxide (KOH) slides. Findings include: 1. No QC documents were available to review on KOH preparation slides at the time of survey. 2. An interview with the lab director (CMS 209) on 9/15/22 at 11: 54 AM in the breakroom confirmed controls were not performed on KOH preparation slides .
D5523	PARASITOLOGY CFR(s): 493.1264(a)(d) The laboratory must have available a reference collection of slides or photographs and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens. (d) 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 quality control (QC) documents and staff interview, the laboratory failed to perform or document controls on parasitology as required. Findings include: 1. Review of QC documents revealed no QC records were available on parasitology at the time of the survey for 2021 and 2022 thus far. 2. Interview with the lab director (CMS 209 form) on 9/15/22 at approximately 11:54 a.m. in the breakroom, confirmed QC was not performed on parasitology.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) document review and staff interview, the laboratory director failed to ensure the lab enrolled and participated in PT for all regulated tests or procedures performed. Findings include: 1. PT document review revealed there were no PT performed for Parasitology testing in 2021 and 2022 thus far. 2. An interview with the laboratory director (CMS 209) and the clinical coordinator in the facility's breakroom on 9/15/2022 at approximately 11:50 a.m. confirmed the lack of Parasitology PT for the aforementioned dates.
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 quality control (QC) document review and staff interview, the laboratory director failed to ensure the lab performed and documented QC on potassium hydroxide (KOH) slides and parasitology slides. Findings include: 1. No QC documents were available to review on KOH slides or parasitology slides at the time of survey. 2. An interview with the lab director (CMS 209) on 9/15/22 at 11:54 AM in the breakroom confirmed controls were not performed on KOH or parasitology slides .
D6127	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and staff interview , the technical supervisor (TS) failed to perform annual competency on all testing personnel. Findings include: 1. Review of TP documents revealed the TS failed to perform annual competency in 2021 and 2022 (to date) on TP #3 and #4 (CMS 209 form). 2. Interview with the clinical coordinator in the facility's breakroom on 9/15/22 at 11:46 AM confirmed the competencies were not performed on the aforementioned TP for the 2021 and 2022 (to date) time periods.