Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D0904401	**(X3) Date Survey Completed** 09/23/2021
Name of Provider or Supplier Dermatology Spcecialists Of Georgia, Llc	**Street Address, City, State** 2550 Windy Hill Rd Suite 220, Marietta, 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 23, 2021. 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:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency testing (PT) attestation document review and staff interview, the lab failed to rotate with all testing personnel, the PT testing done in 2020 and 2021 for the subspecialty of mycology #120 Finding include: 1. Review of the College of American Pathology (CAP) PT attestation documents reveals the LD performed two (2) of two (2) testing events done in 2020 and 2021 (2020 #2 and 2021 #1). 2. Interview with the office manager on 9/23/21 at approximately 12:05 PM in the lab, confirmed the LD performed the aforementioned PT.
D2021	BACTERIOLOGY CFR(s): 493.823(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of

	patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on College of American Pathology (CAP) proficiency testing (PT) document review and staff interview, the laboratory failed to participate in 2020 event one (1) PT event which resulted in a score of Zero (0) for Mycology #120. Findings include: 1. Review of CAP PT documents reveals the laboratory failed the subspecialty of Mycology #120 on 2020 event #1 with score of 0%. 2. Interview with the office manager in the laboratory on 9/23/2021 at approximately 12:20 p.m. confirmed the lab failed to participate in 2020 PT event #1.
D2039	MYCOLOGY CFR(s): 493.827(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on College of American Pathology (CAP) proficiency testing (PT) document review and staff interview, the laboratory failed to participate in 2020 event one (1) PT event which resulted in a score of Zero (0) for Mycology #120. Findings include: 1. Review of CAP PT documents reveals the laboratory failed the subspecialty of Mycology #120 on 2020 event #1 with score of 0%, due to non-participation. 2. Interview with the office manager in the laboratory on 9/23/2021 at approximately 12: 05 p.m. confirmed the lab failed to participate in 2020 PT event #1.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) result document review and staff interview, the lab failed to review PT results as received from the PT provider. Finding include: 1. Review of the College of American Pathology (CAP) PT result documents reveals the LD failed to document review of testing events done in 2020 and 2021 (2020 #2 and 2021 #1). 2. Interview with the office manager on 9/23/21 at approximately 12:05 PM in the lab, confirmed the aforementioned lack of PT result review.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to ensure reagents and solutions not be used after their expiration date. Findings include: 1. Observation during the laboratory tour on 9/23/2021 at approximately 10:05 a.m. revealed a bottle of Potassium Hydroxide (KOH) 10 percent reagent lot #9220-02 in the laboratory cabinet above the microscope which had expired on 1-31-21. Observation during the same tour at 10:05 a.m. on 9/23/2021 revealed Green Tissue Marking Dye lot #079095 with the expiration date of 3/1/21 in the dye rack near the Avantik QS12 cryostat. 2. An interview with the office manager in the laboratory on 9/23/2021 at approximately 12:20 p.m. confirmed the KOH solution in use had expired and the Green Tissue Marking Dye in use had expired.
D5517	MYCOLOGY CFR(s): 493.1263(a)(c) The laboratory must check each batch (prepared in-house), lot number (commercially prepared), and shipment of lactophenol cotton blue when prepared or opened for intended reactivity with a control organism(s). (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on testing log 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 slides at the time of survey. 2. Interview with the office manager on 9/23/21 at 11:40 AM in the lab, confirmed controls were not performed on KOH slides .
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 lab report review and staff interview, the laboratory failed to include all the required information on the in-house laboratory test reports. Findings include: 1. Review of 3 in-house test reports (#07191945, #469898, & #511540) for MOHS histopathology mapping report and potassium hydroxide (KOH) fungal reports,

	reveals the lack of testing location name and address. 2. Interview with the office manager in the lab on 9/23/21 at 11:43 AM, confirmed the lack of testing location name and address on in-house testing reports.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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 testing personnel (TP) documents and an interview with the office manager, the lab director failed to perform documented training on all testing personnel in the subspecialty of mycology #120. Findings include: 1. Review of personnel documents available revealed the lack of documented training on staff #3 (CMS 209). 2. Interview with the office manager in the lab on 9/23/21 at 12:05 PM, confirmed the lack of training documentation.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate 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 an interview with the lab director, the technical consultant failed to perform semiannual competency on all testing personnel. Findings include: 1. Review of TP documents revealed the lack of documented 6 month competency on staff #3 (CMS 209). 2. Interview with the office manager in the lab on 9/23/21 at 12:05 PM, confirmed the lack of 6 month competency documentation.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and staff interview , the technical consultant failed to perform annual competency on all testing personnel. Findings include: 1. Review of TP documents revealed the lack of documented annual

	competency on staff #3 (CMS 209) for the years of 2019, 2020, and 2021 thus far. 2. Interview with the office manager in the lab on 9/23/21 at 12:05 PM, confirmed the lack of annual competency documentation.