Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0686603	05/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates Of Georgia Llc	1951 Clairmont Road, Decatur, 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 May 29, 2019. 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 test (PT) document review and staff interview, the laboratory failed to enroll in a PT program that meets the required (five sample) CLIA criteria. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed the laboratory received and tested only one PT sample for Microbiology Potassium Hydroxide (KOH) skin scraping for the following PT events: 2018 -- all three events; 2019 -- First event (2019-A). 2. An interview with an office manager in a medical office on 5/29/2019 at approximately 1:45 p.m. confirmed the aforementioned lack of required PT samples tested. REPEAT DEFICIENCY
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)

	The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to attest to the routine integration of the PT samples into the patient workload as required. Findings include: 1. American Academy of Family Physicians (AAFP) document review revealed the laboratory failed to produce an attestation statement signed by the LD and testing personnel for the following Clinical Microbiology Potassium Hydroxide (KOH) and Dermatophyte Screen PT events: 2017 -- Off-schedule/Reinstatement PT event; 2017-C, 2018 -- all three PT events; 2019-A. 2. An interview with an office manager in a medical office on 5/29/2019 at approximately 1:45 p.m. confirmed the failure of the laboratory to produce attestation statements signed by the LD and testing personnel for the aforementioned PT events.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of mycology quality control documents and staff interview, the laboratory failed to perform required media quality control. Findings include: 1. Dermatophyte Test Medium (DTM) QC document review revealed the labaoratory failed to check each batch of DTM media for its ability to support or inhibit growth for the following dates: 2017 -- June through December; 2018, 2019 thus far. 2. Dermatophyte Test Medium (DTM) QC document review revealed the labaoratory failed to check each batch of DTM media for sterility for the following dates: 2017 -- June through December; 2018, 2019 thus far. 3. An interview with the clinic manager on 5/29/2019 at approximately 1:45 p.m. in a medical office confirmed the aforementioned lack of QC of DTM media.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of proficiency test (PT) documents and staff interview, the laboratory director (LD) failed to provide overall management and direction of the laboratory as required. Findings include: For detailed refer to D6015 and D6018

D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) 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 review of proficiency test (PT) documents and staff interview, the laboratory director (LD) failed to ensure the laboratory was enrolled in an HHS approved PT program for the testing performed. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed the laboratory received and tested only one PT sample, instead of the five samples required, for Microbiology Potassium Hydroxide (KOH) skin scraping for the following PT events: 2018 -- all three events; 2019 -- First event (2019-A). 2. An interview with an office manager in a medical office on 5/29/2019 at approximately 1:45 p.m. confirmed the aforementioned lack of required PT samples for each PT event.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that 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; This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to ensure that all PT reports received were reviewed by appropriate staff as required. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed the LD failed to review Dermatophyte Screen/Culture PT reports for the following PT events: 2017-B, 2018-B, 2018-C and 2019-A. 2. AAFP PT document review revealed the LD failed to review Clinical Microbiology Potassium Hydroxide (KOH) PT reports for the following PT events: 2018-A, 2018-B, 2018-C, and 2019-A. 3. An interview on 5/29 /2019 with an office manager in a medical office at approximately 1:45 p.m. confirmed the aforementioned failures of LD review of PT reports.
D6071	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(2) Each individual performing moderate complexity testing must maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples.

	This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, testing personnel (TP) failed to maintain records that demonstrate PT samples are tested in the same manner as patient samples. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed TP failed to produce PT records at the time of survey for PT event 2017-C for Dermatophyte Screen/Culture and Microbiology Potassium Hydroxide (KOH) skin scraping. 2. An interview with an office manager in a medical office on 5/29/2019 at approximately 1:45 p.m. confirmed the aforementioned lack of PT document retention.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the Laboratory Director/Technical Supervisor (LD/TS) failed to perform competencies/peer reviews for testing personnel as required. Findings include: 1. Based on TP document review and staff interview, the LD/TS failed to perform competencies or ensure peer reviews were performed for 3 of 3 TP performing Potassium Hydroxide (KOH) testing of laboratory samples for 2017 (June - December); 2018, and 2019 thus far. 2. An interview with an office manager in a medical office on 5/29/2019 at approximately 1: 45 p.m. confirmed competencies nor peer reviews were performed for 3 of 3 TP for the aforementioned dates.