

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0993620	(X3) Date Survey Completed 11/12/2019
Name of Provider or Supplier Dermatology Associates Of Georgia Llc	Street Address, City, State 201 Michael Etchison Road, Monroe, 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 November 12, 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:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to ensure all TP who routinely perform moderate complexity laboratory testing participate in testing of PT samples as required. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed the same TP, who is no longer employed by the facility, performed the Dermatophyte Screen (Mycology) and Skin Scraping (Urinalysis - Potassium Hydroxide) for the following PT events: 2018 -- Events B and C; 2019 -- Events A, B, and C. 2. An interview with the back office medical assistant on 11/12/2019 in the breakroom at approximately 1:00 p.m. confirmed the same TP performed the aforementioned PT testing for 2018 and 2019.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the</p>

proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:
Based on proficiency test (PT) document review and staff interview, the laboratory failed to retain all PT documents as required. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed there was no attestation statement for 2018 Event A for Dermatophyte Screen and Skin Scraping. 2. An interview with the back office manager in the breakroom on 11/12/2019 at approximately 1:00 p.m. confirmed the lack of attestation documentation for the aforementioned PT event.

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 proficiency test (PT) documents and staff interview, the laboratory failed to perform required corrective action for PT results less than one hundred percent. Findings include: 1. American Academy of Family Physicians (AAFP) document review revealed the lack of corrective action for 2018 Event C -- Dermatophyte Screen score of eighty percent (80%). 2. AN interview with the back office medical assistant in the breakroom at approximately 1:00 p.m. on 11/12/2019 confirmed the aforementioned lack of corrective action.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy and procedure manual and staff interview, the laboratory failed to establish required policies and procedures for laboratory testing. Findings include: 1. SOP review revealed the laboratory failed to establish a policy and procedure for the following: quality control (QC) of mycology media -- sterility check and ability to support or inhibit growth. 2. An interview with the back office medical assistant in the breakroom on 11/12/2019 at approximately 1:00 p.m. confirmed the lack of the aforementioned policies and procedures in the laboratory SOP.

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 quality control (QC) documents and staff interview, the laboratory failed to establish required mycology quality control (QC) policies and procedures. Findings include: 1. QC document review revealed the lack of QC documentation for sterility check of dermatophyte test media (DTM) and ability of DTM media to support or inhibit growth for 2018 and 2019, thus far.. 2. An interview with the back office medical assistant in the breakroom on 11/12/19 at approximately 1:00 p.m. confirmed the lack of the aforementioned required QC documentation for 2018 and 2019, thus far.

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/technical supervisor (LD/TS) failed to review PT reports as required. Findings include: 1. American Academy of Family Physicians (AAFP) document review revealed the LD/TS did not review the following PT reports for Dermatophyte Screen and Skin Scraping (Urinalysis -- Potassium Hydroxide): 2018 -- Events A, B, and C; 2019 -- Events A and B. 2. An interview with the back office medical assistant

in the breakroom on 11/12/19 at approximately 1:00 p.m. confirmed the aforementioned lack of PT report review by the LD/TS.

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 technical supervisor/laboratory director (TS/LD) failed to ensure required TP competencies were performed. Findings include: 1. TP competency document review revealed the TS/LD failed to perform competencies --Specialty of Potassium Hydroxide (KOH) testing -- in 2018 and 2019, thus far, for the following TP listed on CMS 209 form -- Staff #4, Staff #5, and Staff #9. 2. TP competency document review revealed there was no documentation available at the time of survey for a second required 2018 Peer Review for Staff #3 (CMS 209). 3. An interview with the back office medical assistant in the breakroom on 11/12/2019 at approximately 1:00 p.m. confirmed the lack of competencies in 2018 and 2019, thus far, for the aforementioned TP. 4. An interview with the lead histotech in the histotech lab area on 11/12/2019 at approximately 12:30 p.m. confirmed the lack of documents for a second required 2018 Peer Review for the aforementioned TP.