

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1027055	(X3) Date Survey Completed 11/20/2019
Name of Provider or Supplier Dermatology Specialists Of Augusta Incorporate	Street Address, City, State 1203 Town Park Lane, Evans, 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 20, 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	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to enroll in an HHS approved PT program for the laboratory testing performed. Findings: 1. Accutest PT document review revealed there was no documentation of enrollment for PT for Parasitology for 2018 and 2019 thus far. 2. An interview with the LD in his office on 11/20/2019 at approximately 6 p.m. confirmed the laboratory was not enrolled in PT for Parasitology for the aforementioned time periods.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks</p>

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 policy and procedure manual (SOP), patient log review, and staff interview, the laboratory failed to follow established policies and procedures for performing quality control (QC) for patient testing as required. Findings include: 1. SOP and Potassium Hydroxide (KOH)/Wet Preparation (Parasitology) patient log review revealed QC was not performed for any daily lab testing for 2018 and 2019 thus far. The SOP requires positive and negative QC to be performed for each day of testing. 2. An interview with the laboratory director in his office on 11/20/2019 at approximately 6:00 p.m. confirmed QC was not performed for the aforementioned laboratory tests for 2018 and 2019 thus far.

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 review of patient logs and staff interview, the laboratory failed to document quality control (QC) for each day of patient testing as required. Findings include: 1. Mycology -- Potassium Hydroxide (KOH) and Parasitology -- Wet Preparation patient log review revealed no QC was performed for KOH and Wet Preparation testing for 2018 and 2019 thus far. 2. An interview with the laboratory director in his office on 11/20/2019 at approximately 6:00 p.m. confirmed there was no QC performed in 2018 and 2019 thus far, for the aforementioned analytes.

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) to ensure annual competencies were performed for TP as required. Findings include: 1. TP competency document review revealed annual competencies were not performed in 2017, 2018, and 2019 for Staff #5 (CMS 209). 2. TP competency document review revealed annual competencies

were not performed in 2018 for Staff #6 (CMS 209) and Staff #7 (CMS 209). 3. An interview with the TS/LD in his office on 11/20/2019 at approximately 6:00 p.m. confirmed the lack of annual competencies in 2017, 2018, and 2019