

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0904401	(X3) Date Survey Completed 05/23/2019
Name of Provider or Supplier Dermatology Specialists 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) Validation survey was completed on May 23, 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 log sheet document review and staff interview, the laboratory failed to enroll in an approved proficiency testing (PT) program for Mycology. Findings include: 1. Review of Mycology log sheet documents revealed no evidence of PT being performed. 2. Interview with the clinical coordinator on 5/23/19 in the histology lab at approximately 11:15 AM confirmed PT was not performed for Mycology.</p>
D5517	<p>MYCOLOGY CFR(s): 493.1263(a)(c)</p> <p>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</p>

control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of Mycology log sheet documents and staff interview, the laboratory failed to check Dermatophyte Test Media (DTM) for intended reactivity with a control organisms. Findings include: 1. Review of Mycology log sheet documents revealed the lab was not performing quality control (QC) on DTM media as required. 2. Interview with the clinical coordinator on 5/23/19 in the histology lab at approximately 11:15 AM confirmed QC was not performed for Mycology (DTM) media.