

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0258633	(X3) Date Survey Completed 09/16/2019
Name of Provider or Supplier Dermatology Consultants Pc	Street Address, City, State 3280 Howell Mill Road, Nw, Suite 101, Atlanta, 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 16, 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:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: After a review of the procedure manual, personnel records and an interview with the clinic administrator, it was determined that the laboratory did not have a comprehensive competency assessment policy with CLIA standards for its testing personnel specific to the specialty of Histopathology. Findings include: 1.) Testing Personnel (TP) record review revealed there was not a competency assessment policy that contained the six (6) CLIA criteria and no annual competencies performed on TPs #2 and #3 (CMS 209) specific to Histopathology (Mohs) processes in 2017, 2018 and 2019. 2.) The clinic administrator confirmed on September 16, 2019, at approximately, 12:15 pm, in the conference room, that the laboratory did not have a competency assessment policy containing the six (6) CLIA criteria specific to Histopathology and did not perform annual competencies for TPs #2 and #3 (CMS 209) in 2017, 2017 and 2019..</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or</p>

procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on Quality Control(QC) slides peer review documents and an interview with the clinic administrator, the laboratory failed to proof that peer reviews were done at least twice a year in 2018. Findings include: 1.) Peer review documents revealed that there were no (QC) slides sent out for review at least twice annually in 2018. 2.) An interview with the histotech and clinic administrator, in the conference room, at approximately 12:17 pm, on September 16, 2019 confirmed that the laboratory had no proof that (QC) slide peer review was completed at least twice annually in 2018.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

A review of the procedure manual and an interview with the clinic administrator confirmed that the laboratory failed to have a Quality Assurance (QA) policy specific to the specialty of Histopathology in 2017, 2018 and 2019. Findings include: 1.) Procedure manual review revealed that the clinic does not have a (QA) policy specific to the specialty of Histopathology for 2017, 2018 and 2019. 2.) An interview with the histotech and clinic administrator, at approximately at 12:20 pm, on September 16, 2019, in the conference room, confirmed that the clinic did not have a written QA policy specific to Histopathology for years 2017, 2018 and 2019.