

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0991500	<b>(X3) Date Survey Completed</b>  02/04/2020
<b>Name of Provider or Supplier</b>  Dermatology Specialists Of West Ga	<b>Street Address, City, State</b>  109 Professional Place, Carrollton, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Provider Performed Microscopy (PPM) Clinical Laboratory Improvement Amendments (CLIA) survey was completed on February 4, 2020. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of quality control (QC) logs, observation during the laboratory tour, review of laboratory test package insert, and staff interview, the laboratory failed to follow current manufacturer instructions for the waived test performed by the laboratory. Findings include: 1. Review of waived test package insert and observation during the laboratory tour on 2/04/2020 at approximately 1:00 p.m. revealed there were no required QC logs available at the time of survey for Human Chorionic Gonadotropin (Consult Diagnostics) for 2019 and 2020 thus far. 2. An interview with the lab director in the lab at approximately 1:00 p.m. on 2/04/2020 confirmed the lack of QC documents for the aforementioned waived test for 2019 and 2020 thus far.</p>
<b>D5209</b>	<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>

This STANDARD is not met as evidenced by:  
Based on review of the procedure document, the lack of testing personnel (TP) documents, and subsequent staff interview, the laboratory failed to establish a policy and procedure to assess TP competency as required. Findings include: 1. Review of the procedure document revealed there was no policy and procedure to assess TP competency available at the time of survey. 2. Lack of TP competency documents revealed there was no annual competency performed for 2 of 2 Staff (CMS 209) for 2019, and 2020 thus far. 3. An interview with the lab director (LD) in the lab on 2/4 /2020 at approximately 1:15 p.m. confirmed the lack of a TP competency policy and procedure at the time of survey. During the same interview, the LD confirmed there were no competency documents available at the time of survey for 2 of 2 Staff (CMS 209) for the aforementioned dates.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:  
Based on laboratory document review and staff interview, the laboratory failed to perform and document equipment maintenance activities as required. Findings include: 1. Laboratory document review revealed there were no routine maintenance documents available at the time of survey for the A/O single ocular microscope for 2019 and 2020 thus far. 2. An interview with the laboratory director on 2/04/2020 in the lab at approximately 1:00 p.m. confirmed the lack of routine maintenance for the laboratory microscope for the aforementioned dates..