

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2047071	(X3) Date Survey Completed 09/26/2018
Name of Provider or Supplier Cole Dermatology, Llc	Street Address, City, State 2410 North Oak Street, Valdosta, 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	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on August 26, 2018. 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:
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: Based on review of the Testing Personnel (TP) competency documents and Policy and Procedures, the laboratory failed to provide competency documents for TP that followed the 6 step competency assessment requirements. Findings: 1. Based on review of the Policy and Procedure manual, the laboratory did not have a written Policy for TP competency and assessment following the 6 step competency assessment requirement. 2. Based on TP competency records, the laboratory did not follow the 6 step competency assessment requirements, and provide documentation of such. 3. Interview with the Laboratory Director (LD) and Practice Administrator, on September 26, 2018 at approximately 5:30pm in the LD's office, confirmed that the laboratory did not have a Policy for TP competency and assessment following the competency assessment requirements. The LD stated that he assessed the competency of each TP when reading slides that the TP submitted for reading. But no formal documentation was provided.</p>
D6065	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p>

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of testing personnel(TP) records, and staff interview, the laboratory failed to provide a copy of the high school diplomas for all TP. Findings: 1. Review of TP records, the laboratory did not have a copy of the high school diploma for two out of three of the TP. 2. Interview with the Laboratory Director (LD) and the Practice Administrator, on August 26, 2018 at approximately 5pm, in the LD's office, confirmed that they did not have a copy of the high school diploma for TP #