

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1078951	(X3) Date Survey Completed 03/23/2018
Name of Provider or Supplier Babcock Dermatology	Street Address, City, State 4890 Roswell Road Ne Suite B 10, 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 March 23, 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: A review of laboratory records and interview with the office manager and Testing Personnel (TP # 2, CMS 209) determined that the laboratory failed to provide annual Competency Assessment for all testing personnel. Findings include: 1. A review of testing personnel records revealed there was no competency evaluations for testing personal for 2016 and 2017. 2. The laboratory failed to have current written policy for semi-annual and annual competencies for testing personnel. 3. An interview with the office manager and TP # 2 (CMS 209) on March 23, 2018 at 12:50 PM in the review room confirmed that there was no current written policy in place and annual competencies were not performed for testing personnel.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:

Based on the review of laboratory maintenance records and interview with the office manager, the laboratory failed to calibrate the Horizon Model 642 Mini E centrifuge annually per manufacturer's recommendations. Findings include: 1. Observation during the laboratory tour revealed the LabCorp Horizon model 642 Mini E centrifuge was last calibrated on December 16, 2014. 2. An interview with the office manager on March 23, 2018 in the surveyor review room at approximately 12:55 PM, confirmed the centrifuge had not been calibrated since 12/16/2014.