

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D1078951	<b>(X3) Date Survey Completed</b>  03/25/2026
<b>Name of Provider or Supplier</b>  Babcock Dermatology	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) Recertification Survey was completed on March 25, 2026. 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:
<b>D6079</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: A review of 2024 - 2025 Personnel Records confirmed that the Laboratory Director failed to ensure that personnel were competent to perform test procedures. THE FINDINGS INCLUDE: 1. A review of 2024 - 2025 Personnel Records found 2 out of 5 personnel competencies were not completed. Competency documentation for HT1 and HT2 (identified on Form 209) was not available on the date of survey. 2. An exit interview, with the personnel, on March 25, 2026, at 12:45pm confirmed that the Laboratory Director failed to ensure that personnel were competent to perform test procedures performed at the laboratory.</p>
<b>D6082</b>	<b>LABORATORY DIRECTOR RESPONSIBILITIES</b>

CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

A review of 2024 - 2026 Temperature Records confirmed that the Laboratory Director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance. THE FINDINGS INCLUDE: 1. A review of 2024 - 2026 Temperature Records revealed temperature failures for the Cryostat without corrective actions documented. 2. A review of 2024 - 2026 Temperature Records confirmed the acceptable temperature range of -20C - -30C. a. A review of 2024 - 2026 Temperature Records revealed that 65 days out of 248 days the recorded temperature for the cryostat was -31C. b. A review of the 2024 - 2026 Patient Logs revealed that on 57 of the 65 days in which the temperature was outside of testing limits, patients testing was performed. 5. An exit interview, with testing personnel, on March 25, 2026, at 12:45pm, confirmed that the Laboratory Director failed to ensure that test systems, developed and used for each of the tests performed in the laboratory, provided quality laboratory services for all aspects of test performance.