

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2042242	<b>(X3) Date Survey Completed</b>  08/31/2022
<b>Name of Provider or Supplier</b>  Advanced Biomedical	<b>Street Address, City, State</b>  2773 Marshall Drive, Suite B, Tifton, 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 August 31, 2022. 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>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologist (CAP) Proficiency Testing (PT) report and staff interview, the Laboratory failed to at least twice annually, verify the accuracy of any test or procedure it performs. The laboratory did not verify the 2021 (SCDD-A) Synthetic Cannabinoid/Designer Drug or 2021 (SCBB-B) Synthetic Cannabinoid/Designer Drug, Findings: 1. Review of the CAP PT results for the 2021 (SCDD-A) Synthetic Cannabinoid/Designer Drug and 2021 (SCBB-B) Synthetic Cannabinoid/Designer Drug, the laboratory received scores that were educational challenges or the test was not in their test menu. The PT results did not verify the accuracy of the Synthetic Cannabinoid/Designer Drugs. 2. Phone Interview with staff # 3 (CMS form 209), the Laboratory Director, and the Owner, on August 31, 2022, in the facility Conference room, at approximately 1pm, confirmed the aforementioned statements.</p>
<b>D6005</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(c)</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</p>

test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

This STANDARD is not met as evidenced by:

Based on review of the College of American Pathologist (CAP) Proficiency Testing (PT) reportb and staff interview, the Laboratory failed to at least twice annually verify the accuracy of any test or procedure it performs. The laboratory did not verify the 2021 (SCDD-A) Synthetic Cannabinoid/Designer Drug or 2021 (SCBB-B) Synthetic Cannabinoid/Designer Drug. The Laboratory Director (LD) is responsible for the overall operation and administration of the laboratory. Findings: 1. Review of the CAP PT results for the 2021 (SCDD-A) Synthetic Cannabinoid/Designer Drug and 2021 (SCBB-B) Synthetic Cannabinoid/Designer Drug, the laboratory received scores that were educational challenges or the test was not in their test menu. The results did not verify the accuracy of the Synthetic Cannabinoid/Designer Drugs being performed in the laboratory. 2. Phone Interview with staff # 3 (CMS form 209), the Laboratory Director, and the Owner, on August 31, 2022, in the facility Conference room, at approximately 1pm, confirmed the aforementioned statements.