

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0580198	<b>(X3) Date Survey Completed</b>  01/07/2026
<b>Name of Provider or Supplier</b>  Advanced Biomedical, Inc	<b>Street Address, City, State</b>  3098 S Harbor Blvd, Santa Ana, CA	
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>D2088</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(b)</p> <p>(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records, CASPER report, and interview with the laboratory director (LD) and technical supervisor (TS); the laboratory failed to attain a score of at least 80 percent of acceptable responses for Sodium analyte in routine chemistry. The findings included: 1. Based on review of PT and CASPER reports, API reported 20% for Sodium analyte for the third event of 2025 (Q3-2025) which is an unacceptable result. 2. Based on the laboratory testing declaration submitted at the time of the survey on 01/07/2025 the laboratory analyzed and reported approximately 1,970 routine chemistry tests which included Sodium analyte during the time the laboratory had unsatisfactory proficiency testing results. 3. The TS affirmed 01/07/2025 at approximately 11:45 a. m. that the laboratory received the above unsatisfactory proficiency testing score</p>
<b>D6082</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)</p> <p>(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;</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the proficiency testing results documentation,</p>

randomly selected patient test records, and interviews with the laboratory director and technical supervisor on January 1, 2025; the laboratory director is herein cited due to failure to ensure that aspects of the analytic phases of the laboratory testing were monitored. The findings include: D2088.