

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0908618	<b>(X3) Date Survey Completed</b>  05/12/2025
<b>Name of Provider or Supplier</b>  Erlanger Health	<b>Street Address, City, State</b>  1720 Gunbarrel Rd, Suite 110, Chattanooga, TN	
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 desk review survey conducted on 05/12/2025 of proficiency testing scores resulted in the following deficiencies. The laboratory was found to be out of compliance with the following conditions: D2016- 493.803 Condition: Successful participation D6000-493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a desk review survey of proficiency testing (PT) records from the Certification and Survey Provider Enhanced Reporting (CASPER) (0155) report and the American Association of Bioanalysts Medical Laboratory Evaluation (AAB/MLE)</p>

	<p>proficiency testing records, the laboratory failed to successfully participate in the platelet (PLT) analyte. Refer to D2130.</p>
<b>D2130</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the CASPER 0155 report and the AAB /MLE 2024 and 2025 PT records, the laboratory failed to achieve satisfactory performance (80% or better) for the same analyte in two consecutive testing events in the specialty of Hematology for the platelet (PLT) analyte. The findings include: 1. A review of the CASPER 0155 report revealed the following results: 2024 Event Three: The laboratory received a 0% score for Platelets. 2025 Event One: The laboratory received a 40% score for Platelets. 2. A review of the AAB/MLE 2024 and 2025 proficiency testing records (Nonchemistry M3 2024 and Nonchemistry M1 2025) confirmed that the laboratory received the above results.</p>
<b>D6000</b>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the CASPER 0155 report and the AAB /MLE 2024 and 2025 records, the laboratory director failed to provide overall management and direction of the laboratory services. The laboratory director failed to ensure that proficiency testing samples were tested as required. Refer to D6016.</p>
<b>D6016</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(i)</p> <p>(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the CASPER 0155 report and the AAB /MLE 2024 and 2025 records, the laboratory director failed to ensure proficiency testing samples were tested as required. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2131.</p>