

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0908618	(X3) Date Survey Completed 01/30/2025
Name of Provider or Supplier Erlanger Health	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints 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: Based on a review of the Laboratory Quality Assurance (QA) Plan, laboratory personnel records, and staff interview, the laboratory director failed to perform competency assessment for the technical consultant in 2023 and 2024. The findings include: 1. The laboratory's "Quality Assurance Plan" policy states: - At least annually, the Laboratory Director will review the performance of each laboratory employee to ensure competency. - Competency will be evaluated initially, at 6 months, and annually thereafter. - Competency will be defined and documented and kept on file. 2. A review of the laboratory personnel records revealed that: - The Technical Consultant (TC) was appointed to the laboratory in February 2023. - No records for documentation of 6-month or annual technical consultant competency by the laboratory director were available for 2023 and 2024. 3. An interview with the office manager, the technical consultant, and testing personnel #1 on 1/30/2025 at 1:15 p.m. confirmed the laboratory director failed to perform competency assessments for the TC in 2023 and 2024.</p>
D6018	LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

This STANDARD is not met as evidenced by:

Based on a review of the laboratory quality assurance (QA) plan, Technical Consultant (TC) Responsibilities, laboratory proficiency testing (PT) records, and staff interview, the laboratory director failed to ensure PT performance evaluations were reviewed and problems requiring corrective action were identified for one of six testing events reviewed in 2023 and 2024. The findings include: 1. The laboratory's Quality Assurance Plan states: - The Laboratory Director or Designee will review the results from both the Proficiency Testing surveys and the alternative performance assessment systems. - Problems identified by proficiency testing and the alternate performance assessment system will be corrected. 2. A review of the Technical Consultant Responsibilities revealed the following: "The Laboratory Director has designated the following responsibilities to the Technical Consultant: - Review of Proficiency Testing" 3. A review of the laboratory's American Association of Bioanalyst/Medical Laboratory Evaluation (AAB/MLE) proficiency testing records revealed the following for the 2024- M3 Non-Chemistry Testing Event: Scores: - Leukocytes- 40% - Platelets- 0% - Eosinophils- 0% Corrective Action: - Could this error affect patient results? Undetermined - PT Failure Classification: Equipment Error ? - No documentation of review by the technical consultant. 4. An interview with the office manager, the technical consultant, and testing personnel #1 on 1/30 /2025 at 1:15 p.m. confirmed that the effect on patient results was not determined, the PT Failure Classification was uncertain, and the performance evaluation had not been reviewed by the technical consultant.