

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1062794	(X3) Date Survey Completed 04/30/2025
Name of Provider or Supplier Piedmont Cancer Institute, Pc	Street Address, City, State 775 Poplar Road, Suite 310, Newnan, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on April 30, 2025. 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:
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) evaluation reports and an interview with the technical consultant (TC), the laboratory failed to document corrective actions for unacceptable hematocrit results received on the 2023 event #3. Findings: 1. Review of the CAP PT 2023 event #3 revealed sample FH10 - 11 had an unacceptable result for hematocrit %. No corrective actions was documented for the missed PT sample. 2. Interview with the TC (CMS 209 form) in the break room at 12:10 pm on 4/30/25 confirmed the finding above.</p>
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <p>(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.</p>

This STANDARD is not met as evidenced by:

Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of all personnel. Findings : 1. An SOP review revealed the LD failed to specify in writing the duties and responsibilities of the Clinical Consultant (CC). 2. An interview with the Technical Consultant (CMS 209) in the break room on 4/30/25 at 12:13 p.m. confirmed the SOP did not contain a duties and responsibilities for the CC.