

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0684710	(X3) Date Survey Completed 04/03/2025
Name of Provider or Supplier Knoxville Pediatric Associates	Street Address, City, State 2201 Clinch Avenue, Knoxville, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), College of American Pathologists (CAP) proficiency testing (PT) records, and staff interviews, the laboratory failed to ensure that nine of ten testing personnel (TP) who routinely performed patient Complete Blood Count (CBC) testing also participated in proficiency testing in 2024. The findings include: 1. Observation of the laboratory on 04.03.2025 at 9:30 a.m. revealed a Sysmex XN-330 analyzer (serial number 14606) for patient CBC testing. 2. A review of Form CMS-209 revealed ten testing personnel (TP10 through TP19) who perform moderately complex patient testing for CBC. 3. A review of the laboratory's CAP PT attestation statements revealed that TP10 was the only testing personnel who participated in hematology proficiency testing in 2024. 4. An interview with the Nurse Manager on 04.03.2025 at 11:15 a.m. confirmed the above survey findings.</p>