

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2175248	(X3) Date Survey Completed 10/02/2025
Name of Provider or Supplier Smg Pediatric Clinic Hardin Valley	Street Address, City, State 2587 Willow Point Way, 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), American Proficiency Institute (API) proficiency testing (PT) records, and staff interviews, the laboratory failed to ensure that two of five testing personnel (TP) who performed hematology patient testing also participated in proficiency testing in 2024. The findings include: 1. An observation of the laboratory on 10.02.2025 at 8:45 a.m. revealed that it used a Sysmex XP-300 hematology analyzer (Serial Number: B5476) for complete blood count (CBC) patient testing. 2. A review of the FORM CMS-209 revealed a total of five persons (TP1, TP2, TP3, TP4, and TP5) who perform moderately complex patient testing. 3. A review of the laboratory's API PT attestation statements revealed that TP4 and TP5 did not participate in any hematology PT events (0 of 3 reviewed) in 2024. 4. An interview with the facility laboratory lead (TP2) on 10.02.2025 at 10:30 a.m. and a subsequent phone interview with the laboratory team lead (TP1) on 10.06.2025 at 1:45 p.m. confirmed the above survey findings.</p>