

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0962575	(X3) Date Survey Completed 10/14/2025
Name of Provider or Supplier Harpeth Pediatrics Pllc	Street Address, City, State 4085 Mallory Lane Suite 204, Franklin, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of the laboratory's procedure manual, quality control (QC) records, lack of records, electronic patient data report, and staff interviews the laboratory failed to follow the procedure for QC used for the Cell-Dyn Emerald instrument used for patient complete blood count with automated differential (CBC w/Diff) testing for one of five dates reviewed in 2025. The findings include: 1. Observation of the laboratory on 10/14/2025 at 10:00 a.m. revealed the Cell-Dyn Emerald (Serial 030225-010950) instrument used for CBC w/Diff patient testing. 2. A review of the laboratory's procedure, "Quality Control Assessment," revealed that the laboratory was required to perform three levels (low, normal, and high) of the Cell-Dyn 18 Plus controls each day and that a minimum of two levels must be within the established range for the run to be acceptable. If the laboratory rejected the run due to QC values that were outside of the established range, the laboratory personnel were required to rerun QC and document all corrective action on the "Corrective Action Log" for review. 3. A review of the laboratory's QC records for 02/03/2025 (one of five dates reviewed) for the lot number 4316 revealed the following: Low (L4316): White blood cell (WBC), Red Blood Cell (RBC), Hemoglobin (HGB), Hematocrit (HCT), Mean Corpuscular Volume (MCV), and Platelet (PLT) analytes were outside of the acceptable ranges. Normal (N4316): RBC, HGB, and HCT analytes were outside of the acceptable ranges. High (H4316): HCT analyte was outside of the acceptable range. 4. On the date of the survey, 10/14/2025, documentation that the laboratory repeated the QC or documented corrective action was not available. 5. A</p>

review of the laboratory's electronic patient data report and an interview with testing person five at 1:30 p.m. on 10/14/2025 revealed that the laboratory performed CBC w /Diff testing for approximately six patients on 02/03/2025. 6. The survey findings were confirmed in an interview with testing person five and the laboratory director on 10/14/2025 at 2:00 p.m.