Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0963636	04/28/2026
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Specialists Of Marion County	325 South Cedar Ave Ste 1, South Pittsburg, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, and staff interviews, the laboratory failed to have a procedure that defined reportable ranges, reference (normal) ranges, and critical ranges for tests performed on the Beckman Coulter DxH 520 hematology analyzer used for complete blood count (CBC) patient testing since August 2024. The findings include: 1. Laboratory observation on 04/28/2026 at 09:50 a.m. revealed the Beckman Coulter DxH 520 (Serial Number BH020095) hematology analyzer used for performing patient CBC

	testing since August 2024. 2. A review of the laboratory procedure manual revealed a CBC testing procedure that lacked defined reportable ranges, reference ranges, or critical value ranges for tests performed on the Beckman Coulter analyzer. 3. The laboratory director confirmed the survey findings in an interview on 04/28/2026 at 1: 30 p.m. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on laboratory observation, review of instrument validation records, review of patient test reports, a review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), and staff interviews, the laboratory failed to validate the reference range data for the Beckman Coulter DxH 520 hematology analyzer before the instrument was placed into use in August 2024, with approximately 3,456 patient complete blood count (CBC) analytes reported annually. The findings include: 1. Laboratory observation on 04/28/2026 at 09:50 a.m. revealed the Beckman Coulter DxH 520 (Serial Number BH020095) hematology analyzer used for performing patient CBC testing. 2. A review of the instrument validation records for CBC testing revealed no normal range validation of the reference intervals that were in use for evaluating the laboratory's patient test results. 3. A review of four patient test reports revealed the following references ranges used for patient evaluation: -White blood cell count (WBC): 3.71-10.67 -Lymphocyte count (LY): 18.94-46.71 -Monocyte count (MO): 4.88-12.81 -Neutrophil count (NE): 40.62-71.65 -Eosinophil count (EO): 0.74-6.73 -Basophil count (BA): 0.05-0.48 -Absolute lymphocyte count (LY#): 1.15-3.52 -Absolute monocyte count (MO#): 0.25-0.99 -Absolute neutrophil count (NE#): 1.85-6.72 -Absolute eosinophil count (EO#): 0.04-0.48 -Absolute basophil count (BA#): 0.00-0.03 -Red blood cell count (RBC): 3.87-5.68 -Hemoglobin (HGB): 12.00-16.75 -Hematocrit (HCT): 35.1-48.7 -Mean corpuscular volume (MCV): 78.4-97.6 -Mean corpuscular hemoglobin (MCH): 26.5-33.5 -Mean corpuscular hemoglobin concentration (MCHC): 32.9-35.4 -Red cell distribution width (RDW): 12.7-15.6 -Red cell distribution width-standard deviation (RDW-SD): 38.9-49.0 -Platelet count (PLT): 150.5-366.8 -Mean platelet volume (MPV): 7.42-10.77 4. A review of the Form CMS-116 revealed that the laboratory performed approximately 3,456 CBC analytes annually. 5. The laboratory director confirmed the survey findings in an interview on 04/28/2026 at 1:30 p.m.