

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0963636	<b>(X3) Date Survey Completed</b>  02/27/2024
<b>Name of Provider or Supplier</b>  Pediatric Specialists Of Marion County	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2007</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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 review of the laboratory's proficiency testing (PT) records, review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS-209), and staff interview, the laboratory failed to ensure PT testing was performed by personnel who routinely perform patient testing for Complete Blood Count (CBC) in 2022 and 2023. The findings include: 1. Review of the laboratory's PT attestation statements and PT testing records revealed that six of six PT events were performed by Testing Person #1. 2. Review of the Form CMS-209 revealed two testing personnel who perform patient testing for CBC. 3. Interview with the Laboratory Director and TP1 on 2/27/24 at 12:10 p.m. confirmed that PT testing was not rotated among both testing personnel who perform patient testing for CBC in 2022 and 2023.</p>
<b>D5203</b>	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on observation of the laboratory, lack of procedures and staff interview, the laboratory failed to establish a policy for maintaining positive patient identification throughout the testing process. The findings include: 1. Observation of the laboratory on 2/27/24 at 09:15 a.m. revealed the Beckman Coulter AcT-Diff 2 Test System (System ID# 62484025) in use for Complete Blood Count (CBC) testing and an unlabeled lavender top Microtainer tube taped to the specimen rocker sitting atop the analyzer. Testing Personnel #1 stated the Microtainer sample to be a recently collected patient specimen. 3. Review of the procedure manual revealed a lack of procedure for specimen labeling. 4. Interview with the Laboratory Director and TP#1 on 2/27/24 at 12:10 p.m. confirmed the current laboratory practice was not to label their specimens with any patient identifiers.

**D5407**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory procedure manual, quality assurance records and staff interview, the laboratory director failed to approve, sign, and date the Quality Assurance Plan before placing into use. 1. Review of the laboratory procedure manual revealed an updated policy entitled "Quality Assurance Plan" that was not signed and approved by the Laboratory Director. 2. Review of the laboratory quality assurance records revealed signed annual Patient Quality Assurance Monitor forms for 2022 and 2023 correlating to the Quality Assurance Plan. 3. Interview with the Laboratory Director and testing personnel #1 on 2/27/24 at 12:10 p.m. confirmed that the Laboratory Director had not signed and approved the updated Quality Assurance Plan.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on review of one patient final test report, and staff interview, the laboratory failed to ensure the laboratory name and address were on the final patient test report. The findings include: 1. Review of the final patient test report for patient #4 revealed the name and address of the laboratory were not on the report. 2. Interview with the Laboratory Director and testing personnel #1 on 2/27/24 at 12:10 p.m. confirmed the laboratory name and address was not included on the final patient test report.