

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 42D1081929	<b>(X3) Date Survey Completed</b> 05/08/2025
<b>Name of Provider or Supplier</b> Palmetto Pediatrics In Blythewood	<b>Street Address, City, State</b> 121 Blythewood Rd, Blythewood, SC	
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>D0000</b>	An onsite CLIA recertification survey was conducted on May 8, 2025, at the laboratory of Palmetto Pediatrics in Blythewood by the South Carolina Department of Public Health's (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with Medicare condition 42 CFR Part 493, CLIA Requirements for Laboratories. The following is a list of Standard level deficiencies cited during the survey:
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory failed to follow its written policy and procedure for employee competency assessments in 2 out of 4 testing personnel listed on the Laboratory Personnel Report (CMS 209 form). Findings included: 1. Review of the laboratory's personnel policy and procedure reveals the statement, "Competency is completed during new hire training, at 6 months of employment, and then annually (each June)". 2. Review of employee competency records reveals 2 out of 4 TP lack initial competency documentation. 3. In an interview on May 8, 2025 at 1:30pm in the laboratory breakroom with the office manager, the findings were confirmed</p>
<b>D5411</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(a)</p> <p>(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results</p>

within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on records review, lack of documentation, and staff interview, the laboratory failed to follow the manufacturer's recommended maintenance schedule for the Sysmex XP-300 hematology analyzer in 8 out of 9 months reviewed from August 2024 to April 2025. Finding Included: 1. Review of the Sysmex XP-300 maintenance log reveals the recommended frequency of cleaning the SRV tray is weakly. 2. Review of the Sysmex XP-300 maintenance logs reveals a lack weekly maintenance documentation in 8 out 9 months reviewed. 3. In an interview on May 8, 2025 in the laboratory's breakroom at 12:30pm with the office manager, the findings were confirmed.