

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0249449	(X3) Date Survey Completed 07/22/2024
Name of Provider or Supplier Palmetto Pediatric & Adolescent Clinic	Street Address, City, State 601 Clemson Rd, Columbia, SC	
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
D0000	An onsite CLIA recertification survey was conducted at Palmetto Pediatrics' clinical laboratory on July 22, 2024, by the South Carolina Department of Public Health's Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirements for Laboratories. The following is a description of STANDARD level deficiencies:
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute's (API) performance scoring and staff interview, the laboratory failed to attain a score of at least 80% of acceptable responses for each analyte in each testing event. Findings included: 1. Document review of API's Performance Summary reveals a failure to successfully participate in the 2022 Hematology/Coagulation 1st event. No results were filed for this event. 2. Document review of the API's Performance Summary reveals a score of 60% for the Leukocyte Count for the 2024 Hematology/Coagulation 1st event. 3. In an interview with the Office Manager (OM) on July 22, 2024, at 12:15pm in the laboratory office, the findings were confirmed.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory</p>

director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on API's Attestation documents for 2022, 2023 and 2024 review and staff interview, the laboratory director (LD) failed to ensure that the appropriate staff reviewed and evaluated the laboratory's proficiency testing (PT) performance.

Findings included: 1. Attestation Statement document was not signed by the LD for the following: a. API's 2022 Hematology/Coagulation 3rd event. b. API's 2024 Chemistry Core 1st event. c. API's 2024 Chemistry Core 2nd event. 2. Review of API's Performance Summary reveals failure to participate for the 2022 Hematology/Coagulation 1st event. No results were filed for this event. 3. No documentation to explain lack of participation for the 2022 Hematology/Coagulation 1st event was available at the time of survey. 4. In an interview with the office manager (OM) on July 22, 2024, at 12:15pm in the laboratory office, the findings were confirmed.