

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 42D0249448	<b>(X3) Date Survey Completed</b> 09/17/2024
<b>Name of Provider or Supplier</b> Palmetto Pediatric & Adolescent Clinic	<b>Street Address, City, State</b> 140 Park Central Drive, Columbia, 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>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a record review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) and an interview with the laboratory compliance officer (CCO) on September 17, 2024, the laboratory director (LD) failed to review and document PT results. The findings include: 1. A review of the laboratory's API records for 2022 Event 3 revealed the laboratory received a score of 80% Core Chemistry (Neonatal Bilirubin). The LD failed to complete and document the review and corrective action form. 2. The laboratory CCO confirmed by interview on September 17, 2024, at 11:00 a.m., the lack of review and signature for the above PT event. 3. The laboratory reports performing 520 Neonatal Bilirubin tests annually.</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of the manufacturer user manuals, and an interview with the laboratory compliance officer (CCO) on September 17, 2024, the laboratory failed to perform and document electrical function checks for three of three patient testing equipment. The findings include: 1. The laboratory failed to perform electrical</p>

function checks which expired on 6/2023 for: a. Sysmex 300 Hematology analyzer, annual electrical check expired 2023. b. Reichert Unistat Bilirubinometer, annual electrical check expired 2023. c. Stat Spin Centrifuge (1) annual, electrical check expired 2023. 2. The laboratory CCO confirmed by interview on September 17, 2024, at 11:00 a.m., the lack of function checks performed for the above patient testing equipment for 2024. 3. The laboratory reports performing 6260 patient tests annually.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review of the CMS-209 Laboratory Personnel form, testing personnel training and competency records, and interview with the compliance officer (CCO) on September 17, 2024, the Technical Consultant (TC) failed to evaluate the competency of all testing personnel, ensuring that the staff maintain their competency to perform test procedures and report test results promptly. The findings include: 1. Record review identified two (2) of nine (9) testing personnel did not have completed annual competency records for moderate complexity testing for Complete Blood Counts (CBC) and Neonatal Bilirubin (NBILI). TP Year/s CBC/NBili #2 2021-2023 No competency records #3 2022 No annual competency 2. The laboratory CCO confirmed by interview on September 17, 2024, at 09:20 a.m., the lack of complete competency assessment records for all testing personnel. 3. The laboratory reports performing 5740 CBC' and 520 NBili tests annually.