

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0249753	(X3) Date Survey Completed 09/18/2024
Name of Provider or Supplier Palmetto Pediatric & Adolescent Clinic, Pa	Street Address, City, State 7448 Broad River, Irmo, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 the laboratory's, the laboratory's testing personnel competency records, the laboratory's Policy and Procedures, and an interview with the laboratory compliance officer (CCO) on September 18, 2024, the laboratory failed to perform testing personnel competency assessments for the six elements listed in the Subpart M for five of five testing personnel. The findings include: 1. The laboratory Quality Assessment plan item #5 "...The personnel will be able to perform all procedures, including performance and reporting of quality control, maintenance procedures, troubleshooting procedures, problem-solving, and patient tests performing and reporting..... The employee will not be allowed to continue performing the procedure until appropriate training has taken place and the employee is deemed competent by the lab director." 2. A review of five testing personnel's competency records revealed that five of the five testing personnel had incomplete competency records, with missing competency review elements or were not reviewed and deemed competent by the lab director (LD) for complete blood counts (CBC) and Neonatal Bilirubin (NBili) for testing personnel as listed on the submitted CMS-209 form: a. TP#1: start date (SD) 2/5/18- 2022, 2023 missing elements: 2022 NBili missing two of six elements reviewed 2022 CBC missing one of six elements reviewed 2023 NBili, CBC missing two of six elements, no LD signature. 2024 Competency due on 8/29/2024, no record at time of survey b. TP#2: SD 1/9/23- 2022, 2023 missing elements: 2023 six-month competency missing five of six elements, no LD signature. 2024 annual Competency NBili/CBC- Missing Assessment of PT/Blind Samples, LD signature. c. TP#3: SD 4/6/15- Annual Competency: 2022 NBili is missing two of six elements. 2022 CBC</p>

missing one of six elements 2023 CBC, NBili competency, no record at time of survey. 2024 NBili, five of six elements missing, CBC four of six elements missing, no LD signature d. TP#4: SD 11/29/21 2022 six-month competency: NBili is missing three of six elements, and CBC is missing two of six elements. 2022 annual competency, no record at time of survey. 2023 annual competency NBili, CBC is missing four of six elements, no LD signature. e. TP#5: SD 7/2/18 2022 annual competency NBili and CBC are missing one of six elements. 2023 annual competency, no record at time of survey. 3. The CCO confirmed, by interview on September 18, 2024, at 3:00 p.m., that the laboratory's policy and procedures for performing testing personnel competency assessments were not being followed. 4. The laboratory reports performing 164 NBili and 1285 CBC patient tests annually.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on a record review of the laboratory's Proficiency testing (PT) policy and procedures, American Proficiency Institute (API) proficiency testing (PT) records, and an interview with the laboratory compliance officer (CCO) on September 18, 2024, the laboratory failed to review and documentation PT results. The findings include: 1. A review of the laboratory's policy and procedure manual identified that the laboratory's Quality Assessment policy #3, Proficiency Testing Assessment and Comparison of Results, states, "The lab Director will review and sign all proficiency testing reports along with all Proficiency Testing failure/corrective Acton forms. 2. A review of the laboratory's PT API records for 2024, 2nd event Hematology /Coagulation, revealed the laboratory received a score of 80% for Hematology (Unacceptable Sample# 6, (Hemoglobin, MCH, MCHC)). The LD failed to sign and date their review on the review and corrective action form. 3. The laboratory CCO confirmed by interview on September 18, 2024, at 2:00 p.m., the lack of review and signature for the above PT events. 4. The laboratory reports performing 1449 patient tests annually.

D5431

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on observation, review of manufacturer user manuals, and an interview with the laboratory compliance officer (CCO) on September 18, 2024, the laboratory failed to perform and document electrical function checks for three of the three pieces of equipment used for patient testing for Complete Blood Count (CBC) and Neonatal Bilirubin (NBILI). The findings include: 1. The laboratory failed to document electrical function checks, which were due on 2/8/2021 for: a. Sysmex XP-300 Hematology analyzer annual electrical check- last performed 1/9/2020, expired 2/8

/2021 b. Reichert Unistat Bilirubinometer annual electrical check - last performed 1/9 /2020, expired 2/8/2021 c. Stat Spin Centrifuge (1) annual electrical check - last performed 1/9/2020, expired 2/8/2021 2. The laboratory CCO confirmed by interview on September 18, 2024, at 2:00 9.m., the lack of function checks being performed for the above equipment for 2022, 2023, and 2024. 3. The laboratory reports performing 1449 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 (CCO) on September 18, 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. A review of five testing personnel's competency records revealed that five of the five testing personnel had incomplete competency records missing elements or had been reviewed and deemed competent by the lab director for complete blood counts (CBC) and Neonatal Bilirubin (NBili). See D5209.