

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D1025342	(X3) Date Survey Completed 09/18/2024
Name of Provider or Supplier Sandhills Pediatrics West Columbia	Street Address, City, State 101 Sum Mor Drive, West 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	Based on the recertification survey conducted on 09/18/2024, at Sandhills Pediatrics West Columbia laboratory and review of the laboratory's plan of correction and evidence of correction recieved on 10/08/2024, the laboratory is found to be in substantial compliance with the CLIA regulatons found at 42 CFR 493 Laboratory Requirements.
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 CMS-209, the laboratory's testing personnel competency records, and an interview with the laboratory compliance officer (CCO) on September 18, 2024, the laboratory failed to follow the laboratory's policy and procedure for conducting testing personnel competency assessments for the six elements listed in the Subpart M for four of twelve testing personnel. The findings include: 1. The laboratory's 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 Twelve testing personnel's competency records revealed that four of the twelve testing personnel had incomplete competency review elements, or were not reviewed and deemed competent by the lab director (LD) for complete blood counts (CBC) and Neonatal Bilirubin (NBili). Testing personnel as listed on the submitted CMS-209 form: a. TP#3: start date (SD) 9/19 /2023, did not have initial and 6-month competency for NBili and CBC testing. b.</p>

TP#8: SD 3/11/2024 , are missing four of six elements in the initial and six (6) month competency: The 2023 six-month competency is missing three of six elements, no LD signature. c. TP#11: SD 6/26/2023- the LD did not review or sign initial competency. The 2024 Six (6) month competency assessment record for NBili and CBC was unavailable at the time of the survey. d. TP#12: SD 2/26/2024 2024 initial competency for NBili and CBC, six (6) of the six (6) elements were not documented as performed. 2024 six-month competency record due August 2024: no records available at the time of the survey. 3. The CCO confirmed, by interview on September 18, 2024, at 12:30 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.

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 the manufacturer user manuals, and an interview with the laboratory compliance officer (CCO) on September 18, 2024, the laboratory failed to perform electrical function checks for two of three patient testing equipment. The findings include: 1. The laboratory failed to perform electrical function checks which expired on 1/4/2023 for: a. Reichert Unistat Bilirubinometer, annual electrical check last performed 1/4/2022, expired 1/4/2023. b. Stat Spin Centrifuge (1) annual, electrical check last performed 1/4/2022, expired 1/4/2023. 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 2023 and 2024. 3. The laboratory reports performing 2759 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 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 record review of the laboratory's CMS Form-209 Laboratory Personnel and the laboratory's testing personnel competency records identified four of twelve testing personnel did not have completed initial, six-month, or annual competency records for moderate complexity testing for the analytes, Complete Blood Counts (CBC) and Neonatal Bilirubin (NBILI). See D5209. Competency Assessment elements: a. Direct observation of test Performance b. Monitor test result recording & reporting c. Review of

worksheets, quality control, maintenance records, b. Direct observaton of instrument maintenance. e. Assessment of test performanc (PT/blind samples) f. Assessment of proble-solving skills records.