

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0249458	(X3) Date Survey Completed 07/22/2024
Name of Provider or Supplier Sandhills Pediatric & Adolescent Clinic	Street Address, City, State 1749 Marshall Street, 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 announced CLIA recertification survey was conducted at the clinical laboratory of Sandhills Pediatrics Columbia on July 22, 2024, 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 42 CFR Part 493, CLIA Requirements for Laboratories. The following is a description of the CONDITION and STANDARD level deficiencies:
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of graded reports from Wisconsin State Laboratory of Hygiene (WSLH), Proficiency Testing Documentation Checklists, and staff interview, the</p>

laboratory failed to successfully participate in a proficiency testing program approved by CMS for Specialty of Hematology, the analyte white blood cell differential (WBC diff). Findings included: 1. Review of the WSLH proficiency testing results from the 2022 (HemeReg1) Hematology 1st event reveals a score as follows: a. WBC auto differential 0% b. Lymphocytes 0% c. Monocyte/Mid-Range Cells 0% d. Granulocytes 0% 2. Review of the WSLH performance summary reveals lack of participation in the WSLH 2023 (HemeReg3) Hematology 3rd event. 0% scores for all analytes for that event. 3. Results of WSLH 2023 (HemeReg3) Hematology 3rd event were confirmed with WSLH via email on 07/24/2024 at 12:25pm. Testing results for subspecialty of Hematology are as follows: a. Leukocytes analyte score 0% b. Erythrocytes analyte score 0% c. Hemoglobin analyte score 0% d. Hematocrit analyte score 0% e. MCV analyte score 0% f. Platelets analyte score 0% Testing results for the subspecialty WBC auto differential are as follows: a. Lymphocyte % score 0% b. Monocyte/Mid-Range Cells % score 0% c. Granulocytes % score 0% 4. Review of the laboratory's "Proficiency Testing Documentation Checklist" reveals lack of online result submission for WSLH 2023 (HemeReg3) Hematology 3rd event. 5. In an interview on July 22, 2024, at 5:00pm in the laboratory office with the office manager (OM), the findings were confirmed.

D2121

HEMATOLOGY
CFR(s): 493.851(a)

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.

This STANDARD is not met as evidenced by:
Based on WSLH Proficiency testing review, laboratory documentation, and staff interview, the laboratory failed to attain a score of at least 80% of acceptable responses for each analyte for each event in 3 of 3 years (2022, 2023, and 2024). Findings included: 1. Review of the WSLH performance summary reveals lack of participation in the WSLH 2023 (HemeReg3) Hematology 3rd event. 0% scores for all analytes for that event. 2. Review of the laboratory's "Proficiency Testing Documentation Checklist" reveals lack of online result submission for WSLH 2023 (HemeReg3) Hematology 3rd event. 3. Results of WSLH 2023 (HemeReg3) Hematology 3rd event were confirmed by WSLH on 07/24/2024 at 12:25pm. The results for Subspecialty Hematology were as follows: a. Leukocytes analyte score 0% b. Erythrocytes analyte score 0% c. Hemoglobin analyte score 0% d. Hematocrit analyte score 0% e. MCV analyte score 0% f. Platelets analyte score 0% Testing results for the subspecialty WBC auto differential are as follows: a. Lymphocyte % score 0% b. Monocyte/Mid-Range Cells % score 0% c. Granulocytes % score 0% 4. In an interview on July 22, 2024, at 5:00pm in the laboratory office with the OM, the findings were confirmed.

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 laboratory document review and staff interview, the laboratory failed to document maintenance and function checks. Findings included: 1. Review of the laboratory's daily, weekly, and monthly checklist revealed no documentation of monthly activities listed for 30 of 30 months reviewed for 2022,2023, and 2024. 2. The activities documented on the monthly checklist included: a. Emergency Lights and Fire Extinguisher check b. Check expiration dates of lab supplies c. Check expiration dates of med supplies d. Check 1 Hgb against CBC e. Check timing on Hct centrifuge f. OSHA Safety Meeting completed g. Compliant reviewed and addressed 3. In an interview on July 22, 2024, at 5:00pm in the laboratory office with the OM, the findings were confirmed.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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 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 review of WSLH attestation documentation, laboratory's "Proficiency Testing Documentation Checklist", 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. American Proficiency Institute's (API) document review reveals attestation statement documents "must be signed by all testing personnel and the laboratory director". 2. Review of laboratory policy and procedure, as part of the laboratory's Quality Assurance (QA) Program reveals: "Proper PT specimen Processing - PT samples are to be handled like patient specimens - Attestation statement is signed and a copy retained - PT results submitted by deadline and copy of report and test records are retained." 3. Document review reveals attestation statement documents have handwritten testing personnel listed, but no signatures of the same personnel for the following events: a. API 2024 Chemistry Core 2nd event. b. API 2024 Chemistry Core 1st event. c. WSLH 2024 Hematology 1st event. 4. Document review revealed lack of Attestation Statement documentation available at the time of survey for WSLH 2023 Hematology 1st event. 5. In an interview on July 22, 2024, at 5:00pm in the laboratory office with the OM, the findings were confirmed.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(6)

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 director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:

Based on review of WSLH Proficiency Testing documentation, laboratory's Proficiency Testing Documentation Checklist, and staff interview, the laboratory director failed to ensure successful participation in a proficiency testing (PT) program approved by CMS. Findings included: 1. Review of WSLH 2023 (HemeReg1) Hematology 1st event score results reveals a score of 0% for the Subspecialty of White Blood Cell (WBC) auto differential as follows: a. WBC auto differential 0% b. Lymphocytes 0% c. Monocyte/Mid-Range Cells 0% d. Granulocytes 0% 2. Review of the WSLH performance summary reveals lack of participation in the WSLH 2023 (HemeReg3) Hematology 3rd event. 0% scores for all analytes for that event. 3. Results of the WSLH 2023 (HemeReg3) Hematology 3rd event were confirmed with WSLH via email on 07/24/2024 at 12:25pm. Testing results for subspecialty Hematology are as follows: a. Leukocytes analyte score 0% b. Erythrocytes analyte score 0% c. Hemoglobin analyte score 0% d. Hematocrit analyte score 0% e. MCV analyte score 0% f. Platelets analyte score 0% Testing results for the subspecialty WBC auto differential are as follows: a. Lymphocyte % score 0% b. Monocyte/Mid-Range Cells % score 0% c. Granulocytes % score 0% 4. Review of the laboratory's "Proficiency Testing Documentation Checklist" reveals lack of online result submission for WSLH 2023 (HemeReg3) Hematology 3rd event. 5. In an interview on July 22, 2024, at 5:00pm in the laboratory office with the office manager (OM), the findings were confirmed.