Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0957415	11/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Sandhills Pediatrics At Dutch Fork	7941 Broad River Road, 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
D0000	An announced onsite CLIA recertification survey was conducted on November 12, 2024, at the clinical laboratory of Sandhills Pediatrics at Dutch Fork 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 list of standard level deficiencies cited:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency testing (PT) documentation, Wisconsin State Laboratory Hygiene (WSLH) PT documentation, laboratory documentation and staff interview, the laboratory failed to have laboratory director sign off on the attestation statement forms (4 out of 18) from 2022, 2023, and 2024. Findings Included: 1. The following events lack signature of the laboratory director: a. WSLH PT Hematology/Coagulation first event 2022 b. API PT Chemistry Core first event 2023 c. API PT Hematology/Coagulation third event 2023 d. API PT Chemistry Core third event 2024 2 Proficiency testing is performed for Hematology

	and Chemistry three times annually accounting for eighteen total surveys in the time frame reviewed by the surveyor. 3. In an Interview on November 12, 2024, in the laboratory office with the office manager, the findings were confirmed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on laboratory environmental monitoring documentation and staff interview, the laboratory failed to document any corrective action taken when the room temperature was not within acceptable limits. Findings included: 1. The acceptable temperature range for room temperature for the laboratory was documented as 20-27 degrees Celsius. 2. Review of three consecutive months in 2022 revealed the room temperature (RT) was outside acceptable limits for 45 out of 90 days as follows: a. June 3, 2022 RT 19.5 degrees Celcius (C) b. June 8, 2022 RT 19.7 C c. June 9, 2022 RT 19.4 C d. June 13, 2022 RT 19.7 C e. June 14, 2022 RT 19.8 C f. June 15, 2022 RT 19.7 C g. June 16, 2022 RT 19.5 C h. June 21, 2022 RT 19.2 C i. June 23, 2022 RT 19.9 C j. June 24, 2022 RT 19.9 C k. June 29, 2022 RT 19.8 C l. June 30, 2022 RT 19.3 C m. July 1, 2022 RT 19.8 C n. July 6, 2022 RT 19.6 C o. July 7, 2022 RT 19.8 C p. July 8, 2022 RT 19.6 C q. July 11, 2022 RT 19.6 C r. July 12, 2022 RT 19.8 C s. Jully 13, 2022 RT 19.4 C t. July 14, 2022 RT 19.3 C u. July 18, 2022 RT 19.8 C v. July 19, 2022 RT 19.9 C w. July 20, 2022 RT 19.4 C x. July 21, 2022 RT 19.6 C y. July 22, 2022 RT 19.6 C z. July 25, 2022 RT 19.7 C aa. July 27, 2022 RT 19.7 C bb. July 28, 2022 RT 19.6 C cc. July 29, 2022 RT 19.7 C dd. August 1, 2022 RT 19.9 C ee. August 2, 2022 RT 19.9 C ff. August 3, 2022 RT 19.3 C gg. August 4, 2022 RT 19.8 C hh. August 8, 2022 RT 19.8 C ii. August 9, 2022 RT 19.4 C jj. August 11, 2022 RT 19.8 C kk. August 12, 2022 RT 19.7 C ll. August 16, 2022 RT 19.8 C mm. August 17, 2022 RT 19.7 C nn. August 18, 2022 RT 19.9 C oo. August 22, 2022 RT 19.7 C pp. August 23, 2022 RT 19.9 C qq. August 24, 2022 RT 19.8 C rr. August 29, 2022 RT 19.9 C ss. August 31, 2022 RT 19.8 C 3. In an interview on November 12, 2024, in the laboratory office with the office manager, the findings were confirmed.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by:

	Based on the lack of documentation and staff interview, the laboratory director failed to sign the procedure manual for the moderately complex laboratory. Findings included: 1. Review of the laboratory procedure manual revealed a lack of documentation that the laboratory director had reviewed or signed off the manual. 2. According to the CMS 209 personnel report form, MD1 is listed as the laboratory director for the moderately complex laboratory. 3. In an interview on November 12, 2024, in the laboratory office with the office manager, the findings were confirmed.