Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0251967	05/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
Grand Strand Pediatrics & Adolescent	8120 Rourke Street, Myrtle Beach, 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 recertification survey was conducted at Grand Strand Pediatrics & Adolescent by South Carolina Department of Public Health (SC DPH) and Bureau of Nursing Homes and Medical Services on May 15, 2025. The facility was found to be out of compliance with the Medicare Condition at 42 CFR Part 493 Laboratory Requirements. The following is a list of CONDITION and STANDARD LEVEL deficiencies cited as a result of May 15, 2025, recertification survey.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on records review and staff interview, the laboratory failed to enroll in a proficiency testing program approved by HHS for the specialties and subspecialities for which it seeks certification for 3 of 3 years reviewed (2023, 2024, and 2025). Findings included: 1. Review of records reveals the laboratory fail to enroll in a proficiency testing program for 3 of 3 years reviewed (2023, 2024 and 2025). 2. In an interview with testing personnel on May 15, 2025, at 2:44 pm in the office the above findings were confirmed.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)

	(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to examine proficiency testing (PT) samples by personnel who routinely perform the testing in the laboratory for random events of the 3 years reviewed (2023, 2024 and 2025). Findings included: 1. Review of CMS 209 personnel report form reveals 7 testing personnel. 2. Review of PT records reveals 3 out of 7 testing personnel performed proficiency testing for 2 out of 3 years examined (2023, 2024 and 2025). a. FH1-A-2023 01-05-2023 results 96% b. FH1-B-2023 06-10-2023 results 95% c. FH1-C-2023 11-15-2023 results 100% d. FH1-A-2024 01-05-2024 results 96% e. FH1-B-2024 06-10-2024 results 100% f. FH1-C-2024 11-15-2024 results 100% g. FH1-A-2025 01-05-2025 results 100% 3. In an interview on May 15, 2025, at 2:25 pm in the office with testing personnel the above findings were confirmed.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on records reviewed and staff interview, the laboratory failed to ensure that the laboratory procedures and changes in procedures were approved, signed and dated by the current laboratory director before use. Findings included: 1. Documentation of the current laboratory director's approval for the use of the laboratory's standard operating procedures regarding all pre-analytic, analytic, and post-analytic phase of testing, quality assurance, quality control, patient test management, and personnel activities were unavailable to review on the day of the survey. 2. Testing personnel confirmed during an onsite interview on May 15, 2025, at 2:44 pm that the laboratory had failed to ensure the reviewed procedures were approved, signed and dated by the current laboratory director.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 direct observation, lack of documentation and staff interview, the laboratory

	failed to verify the accuracy of devices used to monitor temperature and humidity. The laboratory lacked evidence that the thermometer and timer were reliable to meet manufacturer's requirements. Findings included: 1. During a tour of the laboratory on May 15, 2025, at 1:46 pm, the surveyor observed AcuRite Indoor Digital Thermometer for temperature and humidity and a digital kitchen timer. 2. The surveyor requested but the laboratory failed to provide, verification of accuracy for the timer and thermometer used for waived and moderately complex testing. a. Henry Schein hCG Urine Cassette Test package inserts under storage and stability reveal temperature requirements "2-30 degrees C (36-86 degrees F)". Directions for use reveal timing requirements 3 minutes. b. Uricult CLED/EMB, Product No. 1000 package inserts reveal incubator thermometer to be calibrated to maintain a temperature of 97 +/-4 degrees F and Urine Culture-Paddles are to be stored at 45-to-77-degree F(7 to 25 degrees C) before use. c. Occult Blood Test package insert reveals 30 seconds and 2-minute requirements for resulting test. d. Celly-Dyn Emerald hematology analyzer's operator manual on page 60 reveals "to ensure the instrument and reagents function properly, it is important to maintain the temperature between 64 -90 degrees F(18-32 degrees C)". 3. In an interview on May 15, 2025, at 2: 44 pm with testing personnel it was confirmed the thermometer, nor the timer were verified for accuracy.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, records review and staff interview, the laboratory failed to ensure reagents were used within expiration dates for moderately complex Complete Blood Cell Count (CBC) testing 3 of 3 vials viewed. Findings included: 1. A tour of the laboratory was conducted on May 15, 2025, at 1:46 pm, the surveyor observed 3 of 3 Cell-DYN 18 Plus Controls. a. High, Lot#5090, expire 07/18/2025 b. Normal, Lot#5090, expire 07/18/2025 c. Low, Lot#5090, expire 07/18/2025 No open or expiration date written on open vials. 2. Review of package insert reveals the vails are stable for 14 days after opened. 3. In an interview on May 15, 2025, at 1:46 pm in the laboratory with testing personnel the above findings were confirmed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on instrument operator manual review, lack of documentation and staff interview, the laboratory failed to document monthly maintenance on the Cell-Dyn hematology analyzer for thirty-four months reviewed from 2022 through 2025 (June 2022, July 2022, August 2022, September 2022, October 2022, November 2022, and December 2022). Findings include: 1. Review of the Cell-Dyn hematology analyzer operator's manual reveals that all operators should routinely perform scheduled

	maintenance to ensure optimum performance of the instrument including a monthly cleaning and monthly clot prevention. 2. Review of records revealed the laboratory lack sufficient documentation of monthly maintenance had not been documented for thirty-four months reviewed from 2022 through 2025. 3. In an interview with testing personnel on May 15, 2025, at 2:44 pm in the office that the monthly maintenance had been written on a calendar, no other documentation was available for the months reviewed.