Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0706929	05/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Grand Strand Pediatrics Adolescent Med	1120 Glenns Bay Rd Suite 120, Surfside 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 and Adolescent by South Carolina Department of Public Health (SC DPH) and Bureau of Nursing Homes and Medical Services on May 20, 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 20, 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 microbiology urine cultures which it seeks certification for 3 of 3 years reviewed (2023, 2024, and 2025). Findings included: 1. Review of CMS 116 reveals the laboratory performs non-waived testing in the specialty/subspeciality of microbiology. 2. Review of records reveals the laboratory failed to enroll in a proficiency testing program for 3 of 3 years reviewed (2023, 2024 and 2025). 3. In an interview with testing personnel on May 20, 2025, at 1:25 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 3 of 3 years reviewed (2023, 2024 and 2025). Findings included: 1. Review of CMS 209 personnel report form reveals 16 testing personnel (TP). 2. Review of PT records reveals 3 out of 16 testing personnel performed proficiency testing for 3 out of 3 years examined (2023, 2024 and 2025). a. 2023 Hematology /Coagulation-1st Event Attestation sheet dated February 14, 2023, reveals TP2 performed PT test. b. 2023 Hematology/Coagulation-2nd Event Attestation sheet dated May 23, 2023, reveals TP2 performed PT test. c. 2023 Hematology/Coagulation-3rd Event Attestation sheet dated October 10, 2023, reveals TP2 performed PT test. d. 2024 Hematology/Coagulation-1st Event Attestation sheet dated February 13, 2024, reveals TP2 performed PT test. e. 2024 Hematology/Coagulation-2nd Event Attestation sheet dated May 21, 2024, reveals TP2 performed PT test. f. 2024 Hematology/Coagulation-3rd Event Attestation sheet dated October 08, 2024, reveals TP2 performed PT test. g. 2025 Hematology/Coagulation-1st Event Attestation sheet dated February 12, 2025, reveals TP8 performed PT test. h. 2025 Hematology /Coagulation-2nd Event Attestation sheet dated May 20, 2025, reveals TP7 performed PT test. 3. In an interview on April 30, 2025, at 1:25 pm in the office with testing personnel the above findings were confirmed.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on records review and staff interview, the laboratory has failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems for 3 of 3 years (2023, 2024, and 2025) reviewed. Findings included: 1. Review of policies and procedures, personnel competency records and proficiency testing records reveal there is no documentation of ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions. a. No documentation of quality management meetings with minutes documented assessments performed to prove the quality of testing. b. No documentation of assessment/verification that patients are identified accurately. c. No documentation of assessment/verification that test results are accurately reported on patients' chart. d. No documentation that personnel competency policy and procedure are communicated with personnel before assessments are performed. e. No documentation of the monitoring of pre-analytical processes and/or communicating the steps to investigate and correct problems to prevent reoccurrence. f. No

	documentation of written proficiency testing policy and procedures, or the process to investigate when problems are identified.
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 20, 2025, at 1:00 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. Sofia2 Flu+SARS Antigen FIA manufactured by Quidel kit instruction for storage and stability "store at room temp 59 to 86 degrees F (15 to 30 degrees C). b. BD Veritor System Rapid Detection of FluA+B with the BD Veritor Plus Analyzer states "ensure ALL Components are at room temperature (15 to 30 degrees C) when running the test". In the instructions for analyze mode, "allow test to develop for 10 minutes". Incorrect results may occur if development time is less than 10 minutes. c. 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. d. Occult Blood Test package insert reveals 30 seconds and 2-minutes requirements for resulting test. e. Cell-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 20, 2025, at 1:25 pm with testing personnel it was confirmed the thermometer, nor the timer were verified for accuracy. Fahrenheit = F Celsius = C
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the CMS 209 personnel form and interview with TP1 and TP2, the laboratory failed to have a qualified technical consultant for moderately complexity testing for the 3 of 3 years (2023, 2024, and 2025) reviewed. Findings

	included: 1. On May 20, 2025, at 1:25 pm a review of the CMS 209 personnel form revealed the laboratory failed to have a qualified technical consultant for moderate complexity testing for 3 years. Refer D6035
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by: Based on records review, lack of documentation and staff interview with technical consultants (TC1 & TC2), the laboratory failed to have qualified technical consultants for moderate complex testing for 3 of 3 years (2023, 2024, and 2025) reviewed. Findings included: 1. Review of CMS 116 application reveals non-waived testing of moderate complexity is performed in the specialty/subspecialty of microbiology and

	hematology. 2. Review of CMS 209 personnel report form reveals 2 technical consultants. a. TC 1 b. TC 2 3. The surveyor requested and the laboratory failed to provide documents for the qualifications of the 2 technical consultants on the day of the survey. 4. In an interview on May 20, 2025, at 1:25 pm in the office with TC1 and TC2 the above findings were confirmed.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory failed to include all 6 competency assessment criteria as required 493.1451(b)(8)(v) for 3 of 3 years reviewed (2023, 2024, and 2025). Findings included: 1. Review of lab " personnel competency" forms reveal employees are evaluated by 5 standards of competency. 2. Review of the laboratory's personnel competency form reveals the form lacks 1 of 6 competency assessment criteria's for moderately complex testing performed. 3. In an interview on May 20, 2025, at 1:25 pm in the office with TP1 and TP2 the above findings were confirmed. No other documentation available on day of survey.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory lacks documentation of high school diploma or equivalent on day of survey as required for moderately complex testing 493.1423(b)(4) for 15 out of 16 TPs reviewed. Findings included: 1. Review of the CMS 209 personnel report reveals 16 TP for moderately complex testing. 2. Review of personnel records reveals lack of documentation of bachelor's degree, associate degree, high school diploma or equivalency as required 493.1423(b)(4) for moderate complex testing on day of survey. 3. In an interview on May 20, 2025, at 1:35 pm in the office with TP1and TP2 the above findings were confirmed.