Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0984119	(X3) Date Survey Completed 12/12/2019
Name of Provider or Supplier Grand Strand Pediatrics & Adolescent	**Street Address, City, State** 4326 Baldwin Avenue, Little River, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: During an onsite recertification on 12/12/2019, based on lack of documentation and testing personnel interview, the laboratory failed to verifiy the accuracy of Uricult testing at least twice annually for 2 of 2 years reviewed (2018, 2019). Findings include: 1. Documentation of a semi-annual test accuracy verification for the Uricult testing for 2018 and 2019 was unavailable for review on the the day of the survey . 2. Testing personnel confirmed during an onsite interview on 12/12/2019 at 2:00pm that the laboratory had failed to verify accuracy of Uricult testing at least twice annually.
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 a policy and procedure manual review, lab record review and testing personnel interview, it was determined that the lab failed to document acceptable

	room and humidity temperature readings for 9 of 24 months reviewed from January 2018 through December 2019 (2018: July, August, September, October, November, December; 2019: January, February, and April) Findings include: 1. A review of the laboratory policy and procedure manual on 12/12/19 revealed that the laboratory room temperature should operate between 68 to 90 degrees Fahrenheit and humidity should operate between 10 to 90 percent. 2. A review of the lab room temperature log on 12 /12/19 revealed that the lab's room temperatures were below 68 degrees Fahrenheit for the following months: a. January 2019: 1 day b. February 2019: 4 days c. April 2019: 1 day d. July 2018: 28 days e. August 2018: 31 days f. September 2018: 30 days g. October 2018: 31 days h. November 2018: 30 days i. December 2018: 31 days Humidity was not documented for the following months: a. July 2018: 28 days b. August 2018: 31 days c. September 2018: 30 days d. October 2018: 31 days e. November 2018: 30 days f. December 2018: 31 day 3. During an onsite interview at 2: 00 pm, testing personnel confirmed that the laboratory had failed to document acceptable room and humidity temperature readings for 9 of 24 months reviewed from January 2018 through December 2019 (2018: July, August, September, October, November, December; 2019: January, February, and April).
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: During an onsite recertification survey on 12/12/2019, based on patient test log review, lack of documentation and testing personnel interview, the laboratory failed to perform quality control checks on each batch of Uricult CLED/EMB agar received prior to patient testing. Findings include: 1. Review of the laboratory's patient test log revealed thatcUricult CLED/EMB testing was routinely performed and reported in the laboratory from July 2017 to the day of the survey. 2. Documentation of quality control checks on each batch of Uricult CLED/EMB agar for its ability to support growth or produce a biochemical response prior to reporting patient results was not available for review on the day of the survey. 3. Testing personnel confirmed during an onsite interview on 12/12/19 at 2:30pm that the laboratory had failed to perform quality control procedures as required.