

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0984119	(X3) Date Survey Completed 10/22/2025
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
D0000	An onsite recertification survey was conducted at Grand Strand Pediatrics and Adolescent Medicine on October 22, 2025. The facility was found to be out of compliance with the Medicare Condition at 42 CFR 493. CLIA Laboratory Requirements. The following is a list of STANDARD Level deficiencies cited as a result of the CLIA recertification survey on October 22, 2025.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, annual test volume, and staff interview, the laboratory failed to establish, approve and follow a written procedure for moderately complex test for Complete Blood Cell Count (CBC) and urine culture(s) before testing patient samples. Findings include: 1. A written and approved procedure for CBC testing was unavailable to review on the day of the survey. 2. A written and approved procedure for urine culture test was unavailable to review on the day of the survey. 3. The laboratory listed an annual volume of 615 CBCs on the CMS 116 form. 4. The laboratory listed an annual volume of 165 bacteriology tests on the CMS 116 form. 5. During an interview on October 22, 2025, at 10:55 am with nurse manager and assistant nurse manager in the office, confirmed that the laboratory failed to establish, approve and follow written procedures for CBCs and urine cultures.</p>
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p>

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:

Based on records review, lack of documentation, and staff interview, the laboratory director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. Findings included: 1. A review of CMS 116 revealed the Cell Dyn Emerald is used for testing CBCs. 2. A review of CMS 116 reveals the Aidian urine paddle system is being used for bacteria colony counts. 3. Review of laboratory documentation reveals the lack of written policies and procedures for the following: a. Step by Step procedure of how to run the Cell Dyn Emerald analyzer to result CBCs. b. Step by Step procedure of how-to setup and result a urine culture with the Aidian uricult paddle system. 4. During an interview on October 22, 2025, at 10:55 am with nurse manager and assistant nurse manager in the office, confirmed that the laboratory failed to establish, approve and follow written procedures for CBCs and urine cultures.