Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0253761	06/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Barnwell Pediatrics	10706 Marlboro Avenue, Barnwell, 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 announced CLIA recertification survey was conducted at Barnwell Pediatrics on June 24, 2026, by the South Carolina Department of Public Health (SC DPH), Bureau of Nursing Homes and Medical Services. The facility was found to be out of compliance with Medicare Condition 42 CFR Part 493, CLIA laboratory requirements. The following STANDARD LEVEL DEFICINCIES were found to be out of compliance as a result of the recertification survey on June 29, 2026:
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, lack of documentation, and staff interview, the laboratory failed to ensure that equipment has not exceeded their expiration date, or deteriorated, or are of substandard quality for 2 out of 2 thermometers used in moderately complex testing procedures. Findings included: 1. During a tour of the laboratory on June 24, 2026, at 1:52 pm the surveyor observed the following thermometers: a. Room thermometer, Fisherbrand, Traceable 2223A0292717, no expiration date available on the day of the survey. b. Refrigerator thermometer, Fisherbrand, Traceable, 281-482-1714, By 420 Due 19 Nov 2021, S/N:192650610 15-078-18411789745 2. The surveyor requested and the laboratory failed to provide calibration/verification of thermometers on the day of the survey. 3. In an interview on June 24, 2026, at 2:46 pm in the office with Technical Consultant the above findings were confirmed.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)

	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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation and staff interview, the laboratory director failed to assess the competency of technical consultants as it relates to the overall operations and administration of the laboratory for 2 out of 2 years reviewed (2025 and 2026). Findings included: 1. Review of the Laboratory Personnel Report Clinical Laboratory Improvement Amendments (CLIA) Center of Medicare & Medicaid Services (CMS) 209 list the following personnel: a. 1 Laboratory Director=LD b. 1 Clinical Consultant=CC c. 1 Technical Consultant=TC d. 4 Testing Personnel=TP 2. The surveyor requested and the laboratory failed to provide competency for 1 out of 1 TC. 3. In an interview on June 24, 2026, at 2:46 pm in the office with Technical Consultant the above findings were confirmed.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interview, the laboratory director failed to write the responsibilities and duties of each consultant and/or persons involved in all phases of the testing process for the 2 out of 2 years reviewed (2025 and 2026). Findings included: 1. Review of CMS 209 Personnel Report reveals the following positions were assigned in the laboratory: a. 1 TC b. 4 TP 2. The surveyor requested and the laboratory director failed to provide written duties /responsibilities for each person involved in all phases of the testing process. 3. In an interview on June 24, 2026, at 2:46 pm in the office with Technical Consultant the above findings were confirmed.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by:

	Based on record review, lack of documentation, and staff interview, the TC failed to ensure the participation of an approved proficiency testing program and/or twice competency verification of Provider Performed Microscopies (PPM) for 2 out of 2 years reviewed (2025 and 2026). Findings included: 1. Review of CMS 209 Personnel report form reveals the following: a. 4 TP 2. The surveyor requested and the laboratory provided documentation for 1 proficiency test event for 3 out of 3 TP performing PPM. The laboratory failed to provide documentation of twice verification of accuracy for PPM testing for the 2 years reviewed. 3. In an interview on June 24, 2026, at 2:46 pm in the office with Technical Consultant 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 record review, lack of documentation, and staff interview, the TC failed to include assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for 2 out of 2 years reviewed (2025 and 2026). Findings included: 1. Review of "Individual Competency Evaluation" form for moderately complex testing reveals the employee (s) are evaluated by "Criteria": a. Specimen handling and processing b. Test Procedure c. Quality Control testing and recording d. Results recording and interpretation e. Instrument maintenance and function checks f. Assessment of problem-solving skills g. Safety Guidelines h. Problem Solving Skills 2. The surveyor requested documentation for assessment of test performance through testing previously analyzed specimens, internal blind test samples or external proficiency testing samples as required 493.1413 but the laboratory failed to provide competency assessment procedure. 3. In an interview on June 24, 2026, at 2:46 pm in the office with Technical Consultant the above findings were confirmed.