

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0919829	(X3) Date Survey Completed 01/08/2025
Name of Provider or Supplier Colonial Family Practice	Street Address, City, State 325 Broad Street, Sumter, 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 CLIA recertification survey was conducted at the clinical laboratory of Colonial Family Practice on January 8, 2025, by the South Carolina Department of Public Health's Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirements for Laboratories.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation, and staff interview, the Supply Storage Room lacked a mechanism to monitor the temperature in the room. Findings included: 1) During a tour of the laboratory on January 8, 2025 at 1:00pm with the office manager, the surveyor recognized the lack of mechanism to monitor the temperature and humidity in the supply storage room. 2) The following is a list of temperature sensitive reagents observed in the supply storage room: a. CTNG 16 kits, lot # B403420, expiration date (exp) 03/31/2026, storage temp (st) 2- 25 C b. Bechman wash solution 10 bottles, lot # M2055441, exp 03/31/2026, st 2-25 C c. Bechman ISE Reference Solution 9 bottles, lot# M402446, exp 06/30/2025, st 2-25 C d. Bechman Mid Standard Solution 12 bottles, lot # M410475, exp 2/28/2026, st 2-25 C. e. Bechman Ethylene Glycol 4 bottles, lot # M402446, exp 2/29/2028 st 2-25 C. f.</p>

Cepheid 5 Kits COV 2FLU/RSV plus, lot # 100144604, exp 8/31/2026, st 15-30 C. g.
Bechman Coulter UniceL DXI Diluent 21boxes, lot # 331613 exp 11/26/2025, st 2-40
C. 3) In an interview with the office manager on January 8, 2025 at 1:00pm in the
laboratory, the findings were confirmed.