

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0253791	(X3) Date Survey Completed 02/24/2026
Name of Provider or Supplier Allendale County Hospital	Street Address, City, State 1787 Allendale-Fairfax Highway, Fairfax, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation, and staff interview, the laboratory failed to identify the expiration date of two types of waived test devices. Reagents, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. Findings included: 1. During the laboratory tour on February 24, 2026, at 1:45 pm the surveyor directly observed two types of waived Testing Devices at room temperature on the counter. a. 3 packs of Quidel Triage D-Dimer Test Devices, Lot #T16149N reference 093025, expiration 2026/7/12 b. 5 packs of Quidel Triage BNP Test Devices, Lot#T15982N reference 9800XR, expiration 5/18/2026 No documentation of date and time Test Devices were placed at room temperature. The facility did not follow manufacturer's instructions as required 493.15(e). 2. Review of package insert for Quidel Triage D-Dimer Test storage and handling requirements reveals "once removed from refrigeration, the pouched Test Device is stable for up to 14 days at room temperature, but not beyond the expiration date printed on the pouch. With a soft, felt tip marker, gently write the date and time of removal from the refrigerator on the pouch and cross out the manufacturer expiration date printed on the pouch. Care must be taken to document the time the product is at room temperature. Once equilibrated to room temperature, do not return the Test Device to refrigeration." 3. In an interview on February 24, 2026, at 3:52 pm with testing personnel (TP1) and CEO the above findings were confirmed.</p>
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 record review, lack of documentation, and staff interview, the laboratory failed to establish and/or verify function checks as defined by the manufacturer for 4 of 4 traceable timers. CLIA requires function checks on devices or instruments used in acceptable methods of operation for clinical testing as stated in 493.1254. Findings included: 1. Review of CMS 116 application reveals Clostridium difficile non-waived moderately complex testing is performed. A review of instructions for completing the C. difficile test requires a timer. 2. 4 Traceable Certificate of Calibration for 99M/59S Timers expired April 23, 2021, and no other documentation was available on day of survey February 24, 2026. 3. In an interview on February 24, 2026, at 3:52 pm with TP1 and CEO the above findings were confirmed.

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(7)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:

Based on record review, and staff interview, the laboratory failed to establish and/or follow procedures for documenting initial competency on new employee(s) in the first year of employment for 2 of 2 years reviewed (2024 and 2025). Findings included: 1. Review of policy and procedures titled "Technical Personnel Competency" review reveals initial competency not included in procedure for new employees. 2. In an interview on February 24, 2026, at 3:52 pm with TP1 and CEO the above findings were confirmed.