

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0253791	(X3) Date Survey Completed 02/10/2026
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
D0000	An unannounced onsite complaint Intake# SC00061813 and recertification survey were conducted at Allendale County Hospital on February 10, 2026, by 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 Conditions at 42 CFR Part 493 CLIA requirements for laboratories. IMMEDIATE JEOPARDY(IJ) was identified on February 10, 2026, for the following CONDITIONS. The IJ CONDITIONS is on-going. D3000 - 42 C.F.R. 493.1101 Condition: Facility Administration D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director. SC00061813 complaint survey
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). This CONDITION is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to meet applicable requirements under 493.1101 through 493.1105, to have a current agreement for transfusion services (D3017); to establish and/or follow arrangements for transfusion services for emergency release blood products (D3019); to confirm positive identification of blood products given during emergency release (D3023); and to perform transfusion reaction investigation for emergency releases of blood products (D3025) for the 17 months reviewed (October 2024 through February 2026).
D3017	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(a)

(a) Arrangement for services. The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products.

This STANDARD is not met as evidenced by:

Based on record review, lack documentation and staff interview, the laboratory failed to establish and/or follow arrangement for transfusion services to provide ABO grouping, D (Rho) typing, unexpected antibody detection, and compatibility testing for emergency release of blood products for 17 months reviewed (October 2024 through February 2026). Findings included: 1. Review of written agreement titled "American Red Cross Blood Services Agreement Between Allendale County Hospital (Customer), and The American National Red Cross, Biomedical Services (ARC), Effective Date: October 1, 2025" reveals customer may contact the ARC Regional Account Manager for the available Reference Laboratory Testing Services which are provided subject to the terms of this Agreement and the then current Reference Laboratory Testing fees. 2. Review of policy and procedures records, the laboratory lacks documentation of transfusion testing services for ABO grouping, D (Rho) typing, unexpected antibody detection, or compatibility testing for the 16 out of 17 patients that received emergency blood transfusion(s). 3. In an interview on February 10, 2026, at 2:45 pm in the conference room with testing personnel TP1 the above findings were confirmed.

D3019

REQUIREMENTS FOR TRANSFUSION SERVICES

CFR(s): 493.1103(b)

(b) Provision of testing. The facility must provide prompt ABO grouping, D (Rho) typing, unexpected antibody detection, compatibility testing, and laboratory investigation of transfusion reactions on a continuous basis through a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.

This STANDARD is not met as evidenced by:

Based on records review, lack of documentation and staff interview, the laboratory failed to establish and/or follow arrangement for transfusion services to provide prompt ABO grouping, D (Rho) typing, unexpected antibody detection, and compatibility testing for emergency release of blood products for 17 months reviewed (October 2024 through February 2026). Findings included: 1. Review of TRANSFUSION SERVICE RECORD and EMERGENCY BLOOD RELEASE FORM, reveals that the laboratory lacks documentation of prompt testing provisions made for 16 out of 17 patients receiving emergency blood. Patients received emergency blood products before ABO grouping, D (Rho) typing, unexpected antibody detection, or compatibility test was performed. No documentation of test results available on day of survey for the following patients transfused as required 493.1103. a. October 17, 2024, MR#00032257, Unit # W180924168630, O negative b. November 3, 2024, MR#32390, Unit# W181724151235, O negative c. December 21, 2024, MR#50635, Unit# W181224132059, O negative d. January 7, 2025, MR#35152, Unit# W181224142053, O negative e. February 7, 2025, MR#48411, Unit# W181724212656, O negative f. April 7, 2025, MR#, Unit# W186225185907, PRBC g. May 19, 2025, MR# 30403, Unit# W181625209469, PRBC h. May 24, 2025, MR#51920, Unit# W181625190435, O negative i. June 20, 2025, MR#41752, Unit# W180925286674 and W181725310119, O negative j. July 12, 2025,

MR#36048, Unit# W181725329120, O negative k. July 21, 2025, MR#4003814, Unit# W181725312435, O negative l. August 2, 2025, MR#00052667, Unit# W186225233505, O negative m. August 5, 2025, MR#53086, Unit# W181225260217, RBC n. August 26, 2025, MR#34995, Unit# W180925301657, RBC o. October 27, 2025, MR#58460, Unit# W181725393271, O negative p. November 26, 2025, MR#42865, Unit# W186225280745, O negative q. December 23, 2025, MR#42865, Unit# W186225302075, O negative 2. In an interview on February 10, 2026, at 2:45 pm in the conference room with testing personnel TP1 the above findings were confirmed.

D3023

REQUIREMENTS FOR TRANSFUSION SERVICES
CFR(s): 493.1103(c)(2)

The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient.

This STANDARD is not met as evidenced by:
Based on policies and procedures reviewed, lack of documentation and staff interviews, the laboratory failed to establish and/or follow policies for ensuring positive identification of recipients receiving blood or blood products when the need for emergency release of blood arises for the 17 months reviewed (October 2024 to February 2026). Findings included: 1. Review of policies and procedures and staff interview reveals lack of documentation for current established procedures and positive identification of recipient receiving blood or blood products. No documentation available on day of survey to meet applicable requirements to perform transfusion reaction investigation procedures for emergency releases blood products. 2. In an interview on February 10, 2026, at 2:45 pm in the conference room with TP1 the above findings were confirmed.

D3025

REQUIREMENTS FOR TRANSFUSION SERVICES
CFR(s): 493.1103(d)

Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.

This STANDARD is not met as evidenced by:
Based on review of policies and procedures and staff interview, the laboratory failed to revise investigation of transfusion reaction procedures for emergency blood release and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. Findings included: 1. Review of policies and procedures titled "Allendale County Hospital Laboratory/BLOODBANK Policies and Procedures" reveals policy dated October 18, 2024 signed and approved by laboratory director for the discontinuing of High Complexity Testing procedures. 2. The surveyor requested and the laboratory failed to provide procedure(s) for the current investigation of transfusion reaction when necessary for emergency blood release. 3. In an interview on February 10, 2026, at 2:45 pm in the conference room with TP1 the above findings were confirmed.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review, lack of documentation, and interview, the laboratory director failed to provide oversight for overall operation and administration of the laboratory when they failed to meet the applicable requirements under 493.1101 through 493.1105 (D6004) during the 17 months (October 2024 to February 2026) reviewed.

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 reappoints 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 interview, the laboratory director failed to fulfill overall operation and administration when the facility failed to meet applicable transfusion requirements during 17 months (October 2024 to February 2026). Findings included: 1. Review of policies and procedures titled "Allendale County Hospital Laboratory/BLOODBANK Policies and Procedures" reveals policy dated October 18, 2024, signed and approved by laboratory director for the discontinuing of High Complexity Testing procedures. Refer to (D3000) 2. The surveyor requested and the laboratory failed to provide a procedure for the current test (s) offered, prompt testing provisions, positive identification of recipients' blood, and investigation of transfusion reaction when necessary for emergency blood release. 3. In an interview on February 10, 2026, at 2:45 pm in the conference room with TP1 the above findings were confirmed.