Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0253791	04/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Allendale County Hospital	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	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) D6076 - HIGH COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1441
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of Centers for Medicare and Medicaid

	Services (CMS) form 0155 and American Association of Bioanalysts (AAB) 2021 and 2022 records, the laboratory failed to successfully participate in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the specialty of Hematology for the Prothrombin Time (PT) analyte and for Immunohematology Compatibility testing. Refer to D2130 and D2181.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CMS form 0155 and American Association of Bioanalysts (AAB) 2022 records, revealed that the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two of three consecutive testing events in the specialty of Hematology for the Prothrombin Time (PT) analyte. Findings included: 1. Review of the CMS 0155 report revealed the following results: Hematology 2022 - 1st Event the laboratory received an unsatisfactory score of 20% for the PT. Hematology 2022 - 3rd Event the laboratory received an unsatisfactory score of 40% for the PT. 2. A review of American Association of Bioanalysts (AAB) 2022 proficiency testing records confirmed the laboratory received the above results.
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the CMS report 155 and American Association of Bioanalysts (AAB) records from 2021 (3rd Event) and 2022(1st Event), revealed that the laboratory failed to achieve satisfactory performance (100%) for the same analyte in two of two consecutive events for Immunohematology Compatibility testing resulting in unsuccessful PT performance. Findings included: 1. Review of the CMS 155 report revealed the following results: 2021 - 3rd Event laboratory received an unsatisfactory score 60% for Compatibility testing. 2022 - 1st Event laboratory received an unsatisfactory score of 80% for Compatibility testing. 2. A review of American Association of Bioanalysts (AAB) 2021 and 2022 proficiency testing records confirmed the laboratory received the above results.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

	This CONDITION is not met as evidenced by: Based on a desk review of laboratory proficiency testing performance revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6089
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing results revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2130 and D2181.