Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0300027	06/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Bibb Medical Center	208 Pierson Avenue, Centreville, AL	

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 laboratory's proficiency testing provider, American Proficiency Institute (API). The laboratory was found to be out of compliance with CONDITION LEVEL DEFICIENCIES, as follows: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director .
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 proficiency testing (PT) desk reviews of the CASPER Reports 0153D and

	0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), and PT evaluation reports from the American Proficiency Institute (API), the laboratory failed to successfully participate (achieve scores of 100%) in proficiency testing for Unexpected Antibody Detection, an analyte in the specialty of Immunohematology. The laboratory failed two out of three PT events in 2024 - 2025, resulting in initial unsuccessful proficiency testing performance. Refer to D2172. .
D2172	UNEXPECTED ANTIBODY DETECTION CFR(s): 493.861(e) (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 proficiency testing (PT) desk reviews of the CASPER Reports 0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), and PT evaluation reports from the American Proficiency Institute (API), the laboratory failed to successfully participate (achieve scores of 100%) in proficiency testing for Unexpected Antibody Detection. The laboratory failed two out of three PT events in 2024 - 2025, resulting in initial unsuccessful proficiency testing performance. The findings include: 1. A review of the CASPER Reports revealed the laboratory received failing scores for Unexpected Antibody Detection in API PT, as follows: A) 2024 Immunology / Immunohematology Event #2: 0% B) 2025 Immunology / Immunohematology Event #1: 80% 2. A review of the laboratory's proficiency testing evaluation reports from the API website confirmed these findings. .
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 proficiency testing (PT) desk reviews of the CASPER Reports 0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), and proficiency testing evaluation reports from the American Proficiency Institute (API), the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D6089. .
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part; This STANDARD is not met as evidenced by: Based on proficiency testing (PT) desk reviews of the CASPER Reports 0153D and

	0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), and PT evaluation reports from the American Proficiency Institute (API), the laboratory director failed to ensure the laboratory had successful participation in an HHS approved proficiency testing program for Unexpected Antibody Detection in two out of three 2024 - 2025 API PT events. Refer to D2172