Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0469307	10/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Hospital Booneville	880 West Main Street, Booneville, AR	

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	A desk review of proficiency testing was performed on October 10, 2022. The laboratory was found to be not in compliance with the following conditions: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6076 - 42 C.F.R. 493.1441Condition: Laboratories performing high 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 review of 2021 and 2022 CMS CASPER Reports 155D, 153D and the

	American Proficiency Institute (API) proficiency testing results, the laboratory failed to successfully participate in three of five proficiency testing events in the specialty Immunohematology for the analyte compatibility testing. Refer to D2181.
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 review of 2021 and 2022 CMS CASPER Reports 155D, 153D and the American Proficiency Institute(API) proficiency testing results, the laboratory failed to achieve satisfactory performance in three of five proficiency testing events for the analyte compatibility testing as evidenced by: A. The laboratory received a score of 60% for compatibility testing in the first proficiency testing event of 2021. B. The laboratory received a score of 80% for compatibility testing in the third proficiency testing event of 2021. C. The laboratory received a score of 80% for compatibility testing in the second proficiency testing event of 2022.
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 review of CMS 155D and API performance evaluation for 2021 and 2022 the laboratory director failed to provide overall management and direction to the lab for successful participation in proficiency testing. 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 record review of CMS 155D and API performance evaluation from 2021 and 2022, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for compatibility testing. Refer to D2181.