Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0041965	12/01/2025
Name of Provider or Supplier	**Street Address, City, State**	
Big Horn Hospital Association	17 North Miles Avenue, Hardin, MT	

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 proficiency testing desk review was completed on December 1, 2025. At the time of the desk review, it was determined that the laboratory was not in compliance with all conditions required by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 Code of Federal Regulations, Part 493 (42 C.F.R. 493). The following condition level deficiency was cited: 493.803 Condition: Successful participation.
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 from the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report and American Proficiency Institute (API) 2025 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 General Immunology for the analyte Rubella Antibody. Refer to D2084.
D2084	GENERAL IMMUNOLOGY CFR(s): 493.837(f) (f) Failure to achieve satisfactory performance for the same analyte or test in 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 proficiency testing desk review of the CASPER 0155 report and the 2025 American Proficiency Institute (API) proficiency testing records, the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte for two consecutive proficiency testing events in the specialty of General Immunology for the analyte Rubella Antibody. Findings: 1. A review of the CASPER 0155 report revealed the following results: General Immunology 2025 - 1st Event: The laboratory received an unsatisfactory score of 60% for Rubella Antibody. General Immunology 2025 - 2nd Event: The laboratory received an unsatisfactory score of 60% for Rubella Antibody. 2. A review of the API proficiency testing records confirmed the laboratory received the above results.