Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0041965	06/08/2026
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 June 8, 2026. At the time of the desk review, it was determined 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. 493. 1441 Condition: 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 a proficiency testing desk review from the Certification and Survey Provider

	Enhanced Reporting (CASPER) 0155 report and the 2025 and 2026 American Proficiency Institute (API) records, the laboratory did not 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 Immunohematology for Compatibility Testing for two consecutive proficiency testing events in 2025 and 2026. Refer to D2181
D2181	COMPATIBILITY TESTING CFR(s): 493.863(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 a proficiency testing desk review of CASPER 0155 report and the 2025 and 2026 American Proficiency Institute (API) proficiency testing records, the laboratory failed to achieve satisfactory performance score of 100% for the same analyte in two consecutive proficiency testing events in the specialty of Immunohematology for Compatibility Testing in 2025 and 2026. Findings: 1. A review of the CASPER 0155 report revealed the following results: Immunohematology 2025-3rd Event, the laboratory received an unsatisfactory score of 80% for Compatibility Testing Immunohematology 2026-1st Event, the laboratory received an unsatisfactory score of 0% for Compatibility Testing 2. A review of the API Proficiency Testing records for 2025 and 2026 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 proficiency testing desk review of CASPER 0155 report and the 2025 and 2026 American Proficiency Institute records, the laboratory director failed to provide overall management and direction of the laboratory services. The laboratory director failed to ensure proficiency testing samples were tested as required for two consecutive proficiency testing events in 2025 and 2026. 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 a proficiency testing desk review of CASPER 0155 report and the 2025 and 2026 American Proficiency Institute records, the laboratory director failed to ensure

	proficiency testing samples were tested as required. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for two consecutive proficiency testing events in 2025 and 2026. Refer to D2181.