Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0689518	11/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Wheatland Memorial Healthcare Laboratory	530 3rd Street Northwest, Harlowton, 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 November 5, 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 an off-site review of the CMS-155 reports of proficiency testing performance, American Proficiency Institute proficiency testing scores, corresponding laboratory records, and email communication with the General Supervisor #1, the

	laboratory failed to achieve satisfactory performance for blood bank compatibility testing for two consecutive proficiency testing events, resulting in an unsuccessful proficiency testing performance in 2025. See 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 an off-site review of American Proficiency Institute (API) proficiency testing (PT) scores and corresponding laboratory proficiency testing records submitted by email on October 31, 2025, by General Supervisor (GS) #1, the laboratory failed to achieve a score of 100% for blood bank compatibility testing for two consecutive events performed in 2025. Findings: 1. A review of API's blood bank PT records on January 02, 2025, revealed the laboratory failed to achieve a satisfactory performance score of 100% for the following events: 2025 Compatibility Testing Event 1 - 80% 2025 Compatibility Testing Event 2 - 80% 2. An email communication with GS #1 on October 31, 2025, at 3:36 PM confirmed the laboratory's unsuccessful proficiency testing scores were due to the failure to resolve weak or inconclusive positive reactions at the time of testing.