

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407818	(X3) Date Survey Completed 08/06/2026
Name of Provider or Supplier Mobridge Regional Hospital	Street Address, City, State 1401 10th Ave West, Mobridge, SD	
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 recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 8/6/26. The Mobridge Regional Hospital laboratory was found not in compliance.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to monitor criteria for acceptable differences between one of three tests performed by multiple methodologies (manual versus automated white blood cell differentials). Those test methods were not compared twice a year in 2025 to determine if their differences were acceptable. Findings include: 1. Review on 8/6/26 of the laboratory's quality assessment (QA) activities revealed the last comparison testing completed for manual versus automated white blood cell differentials was completed in 2023. There were no other comparison testing documented in 2024, 2025, or to date in 2026. A request was made for any additional documentation pertaining to the comparison of white blood cell differentials. No additional documentation was provided during the survey. Review of the annual test volume form revealed 19 manual and 7,757 automated white blood cell differential patient tests were performed in 2025, without the difference between the two test methods being evaluated for acceptability twice yearly. Review on 8/6/26 of the laboratory's Quality Assurance Plan, last approved by the laboratory director 4/8/25, revealed "Analytic Systems- ... Comparison of Test Results- Any test that is performed in the lab using two or more methodologies or instruments will be evaluated two times a year for acceptable correlation." Interview

on 8/6/26 at 11:30 a.m. with laboratory supervisor A revealed the laboratory did not document the twice-a-year comparisons between manual and automated differentials in 2024, 2025, or to date in 2026. She was not aware they had been required.