Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0041551	11/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Milbank Area Hospital/Avera Health	301 Flynn Drive, Milbank, 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 11/12/25. The Milbank Area Hospital/Avera Health laboratory was found not in compliance with the following requirement: D2014.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain a copy of the required documentation related to the processing of 21 of 24 proficiency testing (PT) events reviewed (2024 Microbiology 1st, 2nd, and 3rd events; 2024 Hematology /Coagulation 1st, 2nd, and 3rd events; 2024 Chemistry Core 1st, 2nd, and 3rd events; 2024 Immunology/Immunohematology 1st, 2nd, and 3rd events; 2025 Microbiology 1st and 2nd events; 2025 Hematology/Coagulation 1st and 2nd events; 2025 Chemistry Core 1st and 3rd events; 2025 Chemistry Miscellaneous 1st event; 2025 Immunology/Immunohematology 1st and 2nd events). Findings include: 1. Review on 11/12/25 of the laboratory's 2024 and 2025 American Proficiency Institute (API) PT event records revealed the laboratory was subscribed to PT events through API. PT specimens were processed, and the results were submitted electronically via the company's website upon completion of the testing. The laboratory did not maintain copies of the final electronically submitted testing results for evaluation for the following events: -2024 API Microbiology 1st event. -2024 API Microbiology 2nd

	event. -2024 API Microbiology 3rd event. -2024 Hematology/Coagulation 1st event. -2024 Hematology/Coagulation 2nd event. -2024 Hematology/Coagulation 3rd event. -2024 Chemistry Core 1st event. -2024 Chemistry Core 2nd event. -2024 Chemistry Core 3rd event. -2024 Immunology/Immunohematology 1st event. -2024 Immunology /Immunohematology 2nd event. -2024 Immunology/Immunohematology 3rd event. -2025 Microbiology 1st event. -2025 Microbiology 2nd event. -2025 Hematology /Coagulation 1st event. -2025 Hematology/Coagulation 2nd event. -2025 Chemistry Core 1st event. -2025 Chemistry Core 3rd event. -2025 Chemistry Miscellaneous 1st event. -2025 Immunology/Immunohematology 1st event. -2025 Immunology /Immunohematology 2nd event. Review of the laboratory's PT policy, with a last reviewed date of 1/22/25, revealed it did not address maintaining copies of the printed final result forms. Interview on 11/12/25 at 10:15 a.m. with general supervisor A revealed: a. PT results were submitted electronically after the PT specimens were processed. b. The laboratory had the capability to print a copy of all final PT results submitted for evaluation. c. The laboratory did not print and maintain copies of the final submitted PT results. d. The laboratory only printed and maintained a copy of the preliminary results.