Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0407818	07/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mobridge Regional Hospital	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 7/12/21. The Mobridge Regional Hospital laboratory was found not in compliance with the following requirements: D2015, D5435, and D5471.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) 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. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to maintain a copy of the submitted results for sixty-four of sixty-four proficiency testing (PT) events reviewed (2019 and 2020). These reports documented the results submitted by the laboratory for evaluation by the PT company. Findings include: 1. Review of the laboratory's PT event records on 7/12/2021 revealed: *The laboratory subscribed to PT events through the American Proficiency Testing Institute and the College of American Pathologists. *PT specimens were processed and the results submitted via the company's website upon completion of testing. *The laboratory had completed and received evaluation reports for the following testing events: a. 2019 API PT events -Immunology /Immunohematology- testing events 1, 2, and 3. -Hematology/Coagulation- testing

	events 1, 2 and 3. -Microbiology- testing events 1, 2, and 3. -Chemistry Core- testing events 1, 2, and 3. -Chemistry Miscellaneous- testing events 1 and 2 b. 2019 CAP PT events -UDS 6 Urine Drug Screen Testing, Limited- testing events A and B. -ALC 2 AACC Alcohols/Volatiles- testing events A and B -NB 2 Neonatal Bilirubin, 2 Challenges- testing events A and B -HPS H. pylori Antigen, Stool -J Transfusion Medicine (Comprehensive)- testing events A, B, and C -CM Clinical Microscopy- Testing events A and B -FH 9 Hematology Automated Differentials- testing events A, B, and C -CGL Coagulation, Limited- testing events A, B, and C c. 2020 API PT events -Immunology/Immunohematology- testing events 1, 2, and 3. -Hematology /Coagulation- testing events 1, 2 and 3. -Microbiology- testing events 1, 2, and 3. -Chemistry Core- testing events 1, 2, and 3. d. 2020 CAP PT events -UDS 6 Urine Drug Screen Testing, Limited- testing events A and B. -ALC 2 AACC Alcohols /Volatiles- testing events A and B -NB 2 Neonatal Bilirubin, 2 Challenges- testing events A and B -HPS H. pylori Antigen, Stool -J Transfusion Medicine (Comprehensive)- testing events A, B, and C -CM Clinical Microscopy- Testing events A and B -FH 9 Hematology Automated Differentials- testing events A, B, and C -K 2 Ligand, Limited- testing events A and B -CGL Coagulation, Limited- testing events A, B, and C Interview on 7/12/21 at 2:45 p.m. with the laboratory manager revealed: *She confirmed the laboratory had not kept the submitted result forms for the PT events they had completed. *She printed the submitted result forms for API testing events only. *She discarded the submitted result forms once the PT evaluation forms had been reviewed.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation, interview, and record review the laboratory failed to retain the results of the daily background checks on the Sysmex XS-1000i analyzer for eleven of twelve months (7/12/19 through 6/17/20) to ensure critical operating characteristics that affected the stability of the analyzer met specific criteria defined by the manufacturer. Findings include: 1. Observation on 7/12/21 at 2:55 p.m. of the Sysmex XS-1000i hematology analyzer's electronic files revealed: *The laboratory manager was able to pull up a record of the analyzer's electronic files. *The oldest retained daily background check was dated 6/18/20. * Daily background counts prior to 6/18 /20 were unavailable. *There was no way to verify if the background counts prior to 6 /18/20 had been acceptable. *Increased background counts could lead to inaccurate patient specimen test results. Review of the annual test volume form revealed 7,321 hematology patient test specimens had been reported in 2020. Interview with the laboratory manager on 7/12/212 at 2:55 p.m. revealed: *She stated the XS-1000i was installed in 2014. *She verified daily background counts had not been printed out or

	maintained. *She believed the Sysmex XS-1000i hematology analyzer's memory was sufficient to maintain the required 2 years of background counts. *She confirmed no other log or spreadsheet was available to document the daily background test results.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to verify each lot number or shipment of the potassium hydroxide (KOH) reagent for its positive reactivity to ensure accurate results prior to testing patient specimens for thirty-five of thirty-five months (7/24/18 through 7/13/21). Findings include: 1. Observation on 7/13/21 at 3:15 p.m. revealed a bottle of KOH reagent (lot number 937457, expiration date 8/12/21) was available for use on patient specimens. The bottle of KOH reagent was less than one quarter full. There was no documentation as to whether or not the missing reagent had been used on patient specimens or discarded. Review of available records revealed KOH quality control (QC) had not been documented in 2018 or to date in 2021 for any lot number or different shipments of the same lot number. Review of the annual testing volume survey form indicated approximately seventy-two KOH patient tests had been performed during 2020 without reagent QC to ensure accurate patient test results. Interview at the above time with the laboratory manager revealed: *She confirmed QC had not been performed on the current bottle of KOH reagent before use on patient samples. *She confirmed the laboratory had not performed QC on the KOH reagent as long as she had worked there. She had worked there for approximately twenty-one years.