Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0407818	07/24/2018
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 from 7/23/18 through 7/24/18. The Mobridge Regional Hospital laboratory was found not in compliance with the following requirements: D2009, D5775, D6127, D6128.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) events and interview with testing personnel A, the laboratory failed to ensure the director had signed 6 of 26 forms (American Proficiency Institutue [API] 2017 immunology/immunohematology first event, chemistry miscellaneous first event, chemistry second event, and hematology /coagulation third event, and College of American Pathologists [CAP] S-C-2017 diagnostic immunology third event and 2018 CAP J-A-2018 immunohematology first event PT events) that attested PT samples had been tested in the same manner as patient specimens. Findings include: 1. Review of PT events for 2017 and 2018 revealed the six attestation statements above had not been signed by the laboratory director or designee. Interview on 7/24/18 at 9:30 a.m. with testing personnel A revealed she was designated to sign the attestation statements for all PT testing with the exception of immunohematology that was signed by the lab director. She was unaware the PT forms had not been signed.
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. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on quality assessment (QA) activities review and interview with testing personnel A, the laboratory failed to monitor the differences between three of three tests performed by multiple methodologies or instruments (human chorionic gonadotropin [hCG] qualitative versus quantitative, white blood cell differential manual versus automated, and complete blood counts [CBC] performed on the Sysmex XS-100i versus Sysmex 300). Those methods or instruments had not been evaluated twice a year in 2017 to determine if their differences had been acceptable. Findings include: 1. Review of the laboratory's 2017 twice yearly comparison reports revealed comparison testing had been completed only once for hCG qualitative versus (vs.) quantitative (7/16/17) and once for white blood cell differential manual vs. automated. No comparison testing had been performed for CBCs performed on the Sysmex XS-100i vs. Sysmex 300 during 2017. Review of the laboratory's 2017 quarterly QA activity reports revealed "all comparisons complete and acceptable." Interview on 7/24/18 at 11:40 a.m. with testing personnel A revealed the lab had not performed the twice a year comparisons between methods or instruments. The technologist who normally performed the comparisons was out sick most of 2017.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel files and interview with laboratory personnel A, the technical supervisor failed to evaluate the competency testing personnel B for their level of competency in performing testing done on patient specimens. Findings include: 1. Review of testing personnel B's personnel file revealed he had completed his orientation in 2016. He had a had a competency assessment performed 1/12/17. He had not have a second competency assessment until 3/19/18. Interview at 5:00 p.m. on 7/23/18 with laboratory personnel A revealed the laboratory did not have a competency assessment policy. She was unaware two competency assessments were required in the first year. She believed only a single evaluation was needed on a yearly basis.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

	This STANDARD is not met as evidenced by: Based on review of personnel files, annual test volume form, and interview with laboratory personnel A, the technical supervisor failed to evaluate the competency of testing personnel C for their level of competency in performing testing done on 132 patient specimens performed in 2017. Findings include: 1. Review of testing personnel C personnel file revealed she had not had a competency assessment performed in 2017. Testing personnel C performs only blood gas testing. Review of the annual testing form revealed 132 patient blood gas specimens had been reported during 2017. Interview at 8:05 a.m. on 7/24/18 with laboratory personnel A revealed she was unaware yearly competency assessments were required for testing personnel C.