Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 43D0658934	**(X3) Date Survey Completed** 07/26/2018
Name of Provider or Supplier Faulkton Area Medical Center	**Street Address, City, State** 1300 Oak Street Po Box 100, Faulkton, 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 7/26/18. The Faulkton Area Medical Center laboratory was found not in compliance with the following requirements: D2009, D5775, and D6149.
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, quality assurance (QA) activities review, and interview with testing personnel A and B, the laboratory failed to ensure the director and/or testing personnel had signed 4 of 29 attestation forms (College of American Pathology [CAP] CM-A 2017 clinical microscopy and BNP-A 2017 first event, C-B 2017 general chemistry and therapeutic drugs second event, and C-C2017 general chemistry and therapeutic drugs third event) that attested PT samples had been tested in the same manner as patient specimens for 2017. Findings include: 1. Review of PT events for 2017 revealed four of four attestation statements had not been signed by the laboratory director or designee and or testing personnel (tow of four attestation statements had not been signed by the laboratory director or designee, one of four attestation statements had not been signed by testing personnel, and one of four surveys lacked a signed attestation statement signed by the laboratory director or designee and testing personnel) for the following: %CAP C-C 2017 general chemistry and therapeutic drugs third event and CAP BNP-A 2018 BNP lacked a laboratory director or designee signature. %CAP C-B 2017 general chemistry and therapeutic drugs second event lacked a testing personnel signature. %CAP CM-A 2017 clinical microscopy first event lacked a signed attestation statement signed by the laboratory

	director or designee and testing personnel. Review of the QA reports revealed PT review was not included in the laboratory's QA plan. Interview on 7/26/18 at 12:30 p. m. with testing personnel A and B revealed they were unaware the PT attestation 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 B, the laboratory failed to monitor the differences between five of five tests (sodium, potassium, chloride, creatinine, and glucose) performed by multiple instruments (Siemens EPOC versus Dimension Expand). Those methods or instruments had not been evaluated twice a year in 2017 or to date in 2018 to determine if their differences had been acceptable. Findings include: 1. Review of the laboratory's 2017 and 2018 QA reports revealed comparison testing had not been completed twice a year for sodium, potassium, chloride, creatinine, or glucose between the Siemens EPOC and the Dimension Expand. Interview on 7/26/18 at 11: 40 a.m. with testing personnel B revealed: %The lab used the Siemens EPOC as a back-up analyzer for the Dimension Expand. %She was not aware comparison testing between the two analyzers was required.
D6149	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(1) The director or technical supervisor may delegate to the general supervisor the responsibility for assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, Levy Jennings graphs, and interview the general supervisor failed to review QC records to ensure they had stayed within performance specifications for each chemistry analyte for three of three months reviewed (January 2018 through March 2018). Findings include: 1. Review of the laboratory's 2018 monthly QC reports and Levy-Jennings graphs revealed the following out of range controls: %Troponin I, 1/22/18. %Creatinine Kinase, 1/30/18. %Vancomycin, 1/7/18. %C-Reactive Protein, 1/31/18. %Free Thyroxine, 1/19/18. % Chloride, 1/13/18, 2/3/18. %Potassium, 2/3/18 and 2/26/18. %Amylase, 2/8/18. % Sodium, 2/12/18 and 3/31/18. Further review of the laboratory's Quality and Corrective Action logs revealed there had been no documentation the out of range values had been reviewed, controls rerun, or corrective actions taken. Interview on 7 /26/18 at 11:10 a.m. with testing personnel A and B revealed they were not aware the QC had been out of range. They both agreed the QC should have been reviewed more thoroughly than had been done.