Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0658934	07/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Faulkton Area Medical Center	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 7/14/21. The Faulkton Area Medical Center laboratory was found not in compliance with the following requirement: D5447.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (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 perform two levels of controls or establish an equivalent quality control (QC) method to verify the accuracy of six of six non-waived test methods (D-Dimer, urine microalbumin, urine creatinine, pH, PCO2, and PO2) each day patient testing was performed. Findings include: 1. Review of the laboratory's records revealed: a. The laboratory performed patient D-Dimer testing on the Alere Triage analyzer. *QC results had not been documented 6/5/21. Patient D-Dimer test results had been reported to the provider on that date. *The laboratory's D-Dimer Procedure (last reviewed by the laboratory director on 1/18/21) stated, "Quality Control Policy- Perform external quality checks on test device with each new lot or shipment and at least monthly. Assay two levels of control (normal and abnormal) to ensure reagent integrity and performance." *Review of the manufacturer's Alere Triage D-Dimer Product Insert revealed, "Good Laboratory Practice suggests that external controls should be tested with each new lot or shipment of test materials, or every 30 days, and as otherwise required by your laboratory's standard quality control procedures." *The laboratory had not developed an individual quality control plan (IQCP) which would have

	allowed the laboratory to process QC specimens at the minimum number and frequency required by the manufacturer. *Review of the laboratory's annual test volume form revealed 208 patient specimens had been reported between 6/30/20 and 7/1/21 without QC having been performed to ensure the accuracy of the test results.. b. The laboratory performed patient urine microalbumin/creatinine ratio testing on the DCA Vantage analyzer. *QC results had not been documented 6/22/21. Patient urine microalbumin/creatinine ratio test results had been reported to the provider on that date. *The laboratory's Microalbumin Creatinine Procedure (written 9/14/18, last reviewed by the laboratory director on 2/22/21) stated, "Quality Control Policy: Assay two levels of control (normal and abnormal) to ensure reagent integrity and performance. Perform with each reagent shipment, every new lot or at least once a month." *Review of the Siemens DCA systems Microalbumin/Creatinine Reagent Kit manufacturer's package insert revealed, "Run quality control specimens under the following conditions: -At regular intervals determined by the laboratory procedures. -With each new lot of reagents. -Each time a calibration card is scanned. -To train and confirm performance acceptability for new analysts. -When results do not match the patient's clinical condition or symptoms." *The laboratory had not developed an individual quality control plan (IQCP) which would have allowed the laboratory to process QC at the minimum number and frequency required by the manufacturer. *Review of the laboratory's annual test volume form revealed 86 urine microalbumin and creatinine patient specimens had been reported between 6/30/20 and 7/1/21 without QC having been performed to ensure the accuracy of the test results. c. The laboratory performed patient blood gas (pH, PCO2, and PO2) testing on the Epoc analyzer. *QC results had not been documented on 2/3/21. Patient blood gas results had been reported to the provider on that date. *The laboratory's Epoc System Operating Procedure (written 3/23/15 and last reviewed by the laboratory director on 6/4/21) stated, "Quality control: Three levels of Eurotrol Epoc control. Frequency: Performed with each new lot number of test cards or every month." *Review of the Epoc System Manual revealed "From each lot in each shipment of cards, analyze at least two (2) levels of fluid controls in duplicate using any verified Reader(s)." *The laboratory had not developed an individual quality control plan (IQCP) which would have allowed the laboratory to process QC at the minimum number and frequency required by the manufacturer. *Review of the laboratory's annual test volume form revealed 99 patient blood gas specimens had been reported between 6/30/20 and 7/1/21 without QC having been performed to ensure the accuracy of the test results. Interview on 7/14/21 at 11:15 a.m. with the laboratory manager revealed: *She confirmed QC was performed on a monthly basis, with new shipments, and changes of lot numbers for the above named testing methods. *She confirmed the laboratory had not developed an IQCP for the D-Dimer, urine microalbumin creatinine ratios, or blood gas testing (pH, PCO2 and PO2). *She was not aware QC was required each day of patient testing was performed unless an IQCP had been established.