Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0658932	08/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Marshall County Healthcare Center	413 9th Street, Britton, 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 8/28/19. The Marshall County Healthcare Center laboratory was found not in compliance with the following requirement: D5445.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, procedure review, and interview with the laboratory (lab) supervisor, the laboratory failed to ensure QC had been acceptable prior to reporting patient results during two (June and July 2019) of three months of chemistry QC reviewed. Findings include: 1. Review of the lab's Chemistry Quality Control policy (last revised 6/2015) revealed: *Three levels of controls would be run every 24 hours. *Controls must be run and within set ranges before patient results can be reported out. *The acceptable range had been set at 2.0 standard deviations (SD) from the mean, with two values within 2.0 SD and one value within 3.0 SD being acceptable. Review of the May, June, and July QC chemistry records revealed: *6/20/19: Creatinine level 3 QC had a reported value of -0.27 which was -11.950 SD from the mean. "Rerun same result, 2 of 3 levels OK" was documented as the corrective action. There was no documentation the QC had been repeated and found acceptable prior to processing patient specimens. *7/13/19: Blood urea nitrogen

	(BUN) level 2 had a reported value of 46 which was 3.333 SD from the mean. "Two flexes on one flex is in" was documented as the corrective action. There was no documentation the out of QC range flex had been removed from the analyzer prior to processing patient specimens. Patient specimens could have been processed using the out of QC range reagent. *7/14/19: BUN level 2 had a reported value of 46 which was 3.333 SD from the mean. "2 of 3 QC OK" was documented as the corrective action. There was no documentation the QC had been repeated and found acceptable prior to processing patient specimens. 7/17/19: BUN level 2 had a reported value of 46 which was 3.333 SD from the mean. "Rerun" was documented as the corrective action. There was no documentation the QC had been rerun and found acceptable prior to processing patient specimens. Interview on 8/28/19 at 12:05 p.m. with the lab supervisor revealed she was unaware the out of range QC results had been accepted without further corrective action being taken prior to the processing of patient specimens.