Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D2031570	04/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
James Valley Community Health Center	1000 18th St Sw Suite 27, Huron, 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 4/24/19. The James Valley Community Health 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 review of the Triage analyzer quality control (QC) records and interview with the laboratory manager, the laboratory failed to perform two levels of controls or establish an equivalent quality control method to verify the accuracy of three of three non-waived test methods (D-Dimer, troponin, and creatinine kinase MB fraction [CKMB]) performed on the Triage analyzer each day patient testing was performed. Findings include: 1. Review of theTriage analyser QC records from 11/1/18 through 4 /24/19 revealed: *QC results had not been documented for the D-Dimer test method on eleven days (4/15/19, 4/9/19, 3/27/19, 1/31/19, 1/24/19, 1/14/19, 12/19/18, 12/18 /18, 12/13/18, 12/4/18, and 11/21/18). Patient test results had been reported to the provider on those days. *QC results had not been documented for the Troponin and CK MB test methods on seven days (4/9/19, 1/24/19, 1/14/19, 12/19/18, 12/18/18, 11 /14/18, and 11/2/18). Patient test results had been reported to the provider on those days. Interview on 4/24/19 at 4:30 pm with the laboratory manager revealed current laboratory practice was to perform QC on a monthly basis and whenever a new test kit was put into use. He was not aware QC was required each day patient testing was performed unless an equivalent control method had been established.