Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0409104	06/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bison Community Clinic	105 West Main, Bison, 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 6/21/19. The Bison Community Clinic laboratory was found not in compliance with the following requirement: D5291.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of quality assurance (QA) activities, QA policies, and interview with the laboratory director, the laboratory failed to follow their QA policy to ensure problems within general laboratory systems had been identified, assessed, and corrected for 12 of 12 months reviewed (January 2018 through December 2018). Findings include: 1. Review of the laboratory's 2018 fourth quarter QA activities report revealed: *Personnel competency had not been marked as acceptable or unacceptable. *Proficiency testing (PT) had not been marked as acceptable or unacceptable. *Communications had not been marked as acceptable or unacceptable. *Safety Compliance Review had not been marked as acceptable or unacceptable. *Laboratory staff had not signed the QA forms. *The laboratory director had signed the QA forms on 3/27/19. Review of the current QA policy signed by the laboratory director in March 2018 stated requirements were: *A mechanism would be in place to document and assess problems identified during QA review. *Staff reviewed and signed the QA reports. *Corrective actions would be taken to prevent recurrence of identified problems. *QA was to be overseen on a regular basis by the laboratory director. *A QA calendar would be developed on an annual basis to assist staff with the quarterly QA reports. *Personnel competency annual review would be included in

	the December quarterly review. *PT annual review would be included in the December quarterly review after receipt of the third PT event's results. *Communications review would be completed at a minimum every December and more often depending upon need. *Safety compliance annual review would be listed on the annual QA calendar as being completed as part of the December quarterly review. Interview on 6/21/19 at 10:55 a.m. with the laboratory director revealed he did not know how he had missed the QA forms were not completed when he signed them. He was aware that QA did need to be completed and reviewed each quarter.