Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0407688	08/05/2026
Name of Provider or Supplier	**Street Address, City, State**	
Eureka Community Health Services	200 J Avenue, Eureka, 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 8/5/26. The Eureka Community Health Services laboratory was found not in compliance.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to conduct a risk assessment as part of their Individual Quality Control Plan (IQCP) to verify the accuracy of one of one non-waived test methods (D-Dimer) reviewed. The risk assessment would identify and evaluate the potential failures and sources of error in the testing process which could adversely affect patient results. Findings include: 1. Review on 8/5/26 of the laboratory's Quidel Triage D-Dimer (biomarker for the detection of blood clots) IQCP revealed the D-Dimer IQCP was approved and signed by the previous laboratory director (A) on 3/12/25. The IQCP was reviewed again 8 /25 by the current laboratory director (B) when he took over as laboratory director. The IQCP plan did not include a risk assessment. A request was made during the survey for any documentation related to the risk assessment evaluation. The laboratory staff were unable to provide the requested documentation during the

	survey. Review on 8/5/26 of the 2025 through 2026 technical consultant's monthly reports revealed the technical consultant had reviewed the D-Dimer quality control on a monthly basis. He did not document the lack of a risk assessment in any of his monthly reports. Review on 8/5/26 of the annual test volume form revealed the laboratory had reported 42 D-Dimer patient specimens in 2025. Interview on 8/5/26 at 1:10 p.m. with laboratory manager D revealed she confirmed the laboratory performed external quality control for D- Dimers per their IQCP (monthly and with any new lot or shipment, as required by the manufacturer). She confirmed the laboratory did not have a risk assessment as a part of the IQCP. She was not aware of any documentation related to the performance of a risk assessment for the Quidel Triage analyzer.
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. This STANDARD is not met as evidenced by: Based on record review, policy review, and interview, the laboratory failed to follow their procedure for comparison of acceptable differences between one of one test methods performed by multiple methodologies (manual white blood cell differential versus automated white blood cell differential). The two methods were not compared twice a year in 2025 or to date in 2026 to determine if their differences were acceptable. Findings include: 1. Review on 8/5/26 of the laboratory's 2025 quality assurance (QA) activities revealed there was only one comparison test for white blood cell differential manual versus automated differential performed on 3/1/25. There was no documentation that a second comparison was performed in 2025. A request was made for any additional documentation pertaining to the comparison of white blood cell differentials. No additional documentation was provided during the survey. Review on 8/5/26 of the laboratory's 2026 QA activities revealed there was one comparison test for white blood cell differential manual versus automated differential performed in March 2026. A request was made for any additional documentation pertaining to the comparison of white blood cell differentials. The surveyor was told a second comparison was not scheduled in 2026. Review on 8/5/26 of the laboratory's Quality Assessment policy, last reviewed 8/25 by the current laboratory director, revealed "Analytic Systems Quality Assessment, ...Comparison of Test Results, ... Twice a year, compare test results of same analytes that are tested by more than one method or instrument. Verify the evaluated results meet the criteria established by the laboratory and document any test result comparisons." Review of the annual test volume form revealed twelve manual and 968 automated white blood cell differential patient tests were performed in 2025 without the difference of the two test methods being evaluated for acceptability twice in 2025. Interview on 8/5/26 at 1:10 p.m. with laboratory manager D, revealed the laboratory documented the comparison between manual and automated differentials once in 2025 and again in 2026. She thought the requirement was to perform the comparison only once per year.