Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D2060423	03/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Black Hills Urgent Care - Haines	1730 Haines Avenue, Rapid City, 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 3/26/25. The Black Hills Urgent Care - Haines laboratory was found not in compliance with this requirement: D5445.
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 two of two non-waived test methods (Troponin I and 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 3/26/25 of the laboratory's Quidel Triage Troponin I (biomarker for the detection of cardiac damage) IQCP revealed: *The Troponin I IQCP had been instituted on 3/3/24. *The IQCP had been reviewed again on 6/7/24 by laboratory director A when she took over as laboratory director. *The IQCP plan had not included a risk assessment. *A request was made at that time for any documentation related to the risk assessment evaluation. Laboratory staff were unable to provide the requested documentation during the survey. Review on 3/26/25 of the laboratory's

	Quidel Triage D-Dimer (biomarker for the detection of blood clots) IQCP revealed: *The D-Dimer IQCP had been instituted on 4/5/24. *The IQCP had been reviewed again on 6/7/24 by laboratory director A when she took over as laboratory director. *The IQCP plan had not included a risk assessment. *A request was made at that time for any documentation related to the risk assessment evaluation. Laboratory staff were unable to provide the requested documentation during the survey. Review on 3/26/25 of the annual test volume form revealed: *The laboratory had reported 139 Troponin I patient specimens in 2024. *The laboratory had reported 182 D-Dimer patient specimens in 2024. Interview on 3/26/25 at 2:30 p.m. with laboratory director A revealed: *She confirmed the laboratory performed external quality control (QC) for both analytes as set forth in their IQCPs. *She confirmed the laboratory did not have a risk assessment as a part of either of the IQCPs. Interview on 3/26/25 at the same time with laboratory supervisor B revealed: *He had reviewed the IQCP procedures when he was hired as the laboratory supervisor in 2024. *He confirmed the laboratory did not have a risk assessment as a part of either of the IQCPs. *He was not aware of any documentation related to the performance of a risk assessment for the Quidel Triage analyzer.