Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0924087	04/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Black Hills Surgical Hospital, Llc	216 Anamaria Drive, 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 4/13/21. The Black Hills Surgical Hospital laboratory was found not in compliance with the following requirement: D3031.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on observation, record review, and interview the laboratory failed to retain: *The results of patient specimen testing performed on the Sysmex XS-1000I hematology analyzer for 25 months and 29 days (1/16/19 to 4/13/21) to ensure the accurate entry of patient specimen test results. *The results of the daily background checks on the Sysmex XS-1000I analyzer for 25 months and 29 days (1/16/19 to 4/13 /21) to ensure critical operating characteristics that affected the stability of the analyzer met specific criteria defined by the manufacturer. Findings include: 1. Observation, interview, and demonstration on 4/13/21 at 1:15 PM of the Sysmex XS-1000I hematology analyzer's electronic files revealed: *The laboratory manager was able to pull up a record of the analyzer's electronic files. *The oldest retained patient specimen result was dated 10/2/19. *The oldest retained daily background check was dated 10/3/19. *Patient test specimen results and daily background counts prior to 10/2 /19 were unavailable. *There was no way to verify the accuracy of result entry of patient specimens processed prior to 10/2/19. *There was no way to verify if the background counts prior to 10/3/19 had been acceptable. *Increased background counts could lead to inaccurate patient specimen test results. Review of the annual test volume form revealed 3,988 hematology patient test specimens had been reported in 2020. Interview with the laboratory manger on 4/13/21 at 1:15 PM revealed: *The

	Sysmex XS-1000I hematology analyzer was interfaced to the laboratory information system. *The Sysmex XS-1000I hematology analyzer printer had been turned off. *Patient report results were not printed out or maintained. *Daily background counts were not printed out or maintained. *She believed the Sysmex XS-1000I hematology analyzer's memory was sufficient to maintain the required 2 years of patient data. *No other log or spreadsheet was available to document the patient specimen test results or the daily background test results.