Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0976697	03/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Rapid City Medical Center Llp - South	101 East Minnesota Street, 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 3/19/21. The Rapid City Medical Center LLP - South 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 with the technical consultant, the laboratory failed to retain the results of patient specimen testing performed on the Sysmex XN-330 hematology analzyer for approximately 15 months (January 2019 to 3 /19/21) to ensure the accurate manual entry of patient specimen test results.Findings include: 1. Observation and demonstration on 3/19/21 at 10:45 a.m. of the Sysmex XN-330 hematology analyzer's electronic files revealed: *Laboratory personnel B was able to pull up a record of the analyzers patient specimen results. *The oldest retained patient specimen result was dated 12/12/19. *Patient test specimen results prior to this date were unavailable. *There was no way to verify the accuracy of result entry of patient specimens processed prior to this date. Review of the annual test volume form revealed 6,209 hematology patient test specimens had been reported in 2019. Interview with the laboratory's technical consultant during the survey on 3/19/21 revealed: *The Sysmex XN-330 analyzer had been put into use in January 2019. *The Sysmex XN-330 was interfaced to the laboratory information system. *Only abnormal patient complete blood cell count (CBC) reports or those CBC patient specmens requiring a manual differential were printed and maintained. All other CBC results were shredded. *She believed the Sysmex XN-330 analyzer's memory was sufficient to maintain the required 2 years of patient data.