Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0652518	01/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Big Sandy Medical Center	166 Montana Avenue E, Big Sandy, MT	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to ensure the laboratory was enrolled in an HHS-approved proficiency testing program for Mycology (KOH Preps) and Parasitology (Wet Mount) from January 1, 2020 to January 26, 2022. Findings: 1. Review of Test Volume Report revealed six KOH Preps and six Wet Preps were performed for 2021. 2. Review of Order Choice Utilization Report for 01/01/2020-12/31/2020 showed two KOH Preps and six Wet Preps had been performed. 3. Review of 2020 and 2021 American Proficiency Institute (API) Testing Program records lacked documentation of proficiency testing for KOH Preps and Wet Preps. 4. Interview on January 26, 2022 at 3:00 PM with the TP#1 confirmed the laboratory failed to enroll in an HHS-approved proficiency testing program for Mycology (KOH Preps) and Parasitology (Wet Preps) from January 1, 2020 to January 26, 2022.
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 record review, procedure and interview with Testing Personnel (TP) #1, the laboratory failed to retain patient test records and quality control (QC) records of rheumajet RF Latex Agglutination Test for Rheumatoid Factor (RF) from January 1, 2020 to March 31, 2021. Findings: 1. No patient test records or QC records of rheumajet RF Latex Agglutination Test were available for review from January 1, 2020 to March 31, 2021. 2. Review of Order Choice Utilization Report for 01/01 /2020-12/31/2020, revealed 21 RF patient tests ordered. 3. Review of Rheumajet RF-NCCLS procedure revealed, "Quality Control 1. Prior to each set of determinations, the latex reagents should be tested with each run using the positive and negative controls provided in the kit." 4. Review of Rheumajet RF-NCCLS procedure included a blank template log to document "date, patient id & name, external pos control, external neg control, lot no. exp date, test result, and tech." 5. Interview on January 26, 2022 at 2:00 PM with (TP)#1 confirmed the laboratory failed to retain patient test records and quality control (QC) records of rheumajet RF Latex Agglutination Test from January 1, 2020 to March 31, 2021.