Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0936207	03/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Same Day Surgery Center Llc	651 Cathedral 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	An initial survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 3/15/21. The Same Day Surgery Center LLC laboratory was found not in compliance with the following requirement(s): D5291, D5391, D5791, and D5891.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory staff, the laboratory failed to ensure a procedure had been established so staff knew how to properly perform and document quality assurance (QA) activities taken for general laboratory systems for 6 of 6 months reviewed (October 2020 to March 15, 2021). Findings include: 1. Review of the laboratory's policies and procedures revealed: *Patient testing had begun on 10 /9/20. *There was no policy or procedure for the completion and documentation of general laboratory QA activities. *No QA activities had been documented to ensure the patient specimen test results were accurate since patient testing had started. Interview on 3/15/21 during the survey with the laboratory's technical consultant (TC) and laboratory staff B revealed the laboratory had not written step-by-step procedures for the performance and documentation of general laboratory QA activities. The laboratory had not documented QA activities since patient testing started in October of 2020. The TC agreed staff should have had a procedure to follow, so they could have performed and documented QA activities.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory staff, the laboratory failed to ensure a procedure had been established so staff knew how to properly perform and document quality assurance (QA) activities taken for preanalytical laboratory systems for 6 of 6 months reviewed (October 2020 to March 15, 2021). Findings include: 1. Review of the laboratory's policies and procedures revealed: *Patient testing had begun on 10/9/20. *There was no policy or procedure for the completion and documentation of preanalytical QA activities. *No QA activities had been documented to ensure the patient specimen test results were accurate since patient testing had started. Interview on 3/15/21 during the survey with the laboratory's technical consultant (TC) and laboratory staff B revealed the laboratory had not written step-by-step procedures for the performance and documentation of preanalytical QA activities. The laboratory had not documented QA activities since patient testing started in October of 2020. The TC agreed staff should have had a procedure to follow, so they could have performed and documented QA activities.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory staff, the laboratory failed to ensure a procedure had been established so staff knew how to properly perform and document quality assurance (QA) activities taken for analytical laboratory systems for 6 of 6 months reviewed (October 2020 to March 15, 2021). Findings include: 1. Review of the laboratory's policies and procedures revealed: *Patient testing had begun on 10/9/20. *There was no policy or procedure for the completion and documentation of analytical QA activities. *No QA activities had been documented to ensure the patient specimen test results were accurate since patient testing had started. Interview on 3/15/21 during the survey with the laboratory's technical consultant (TC) and laboratory staff B revealed the laboratory had not written step-by-step procedures for the performance and documentation of analytical QA activities. The laboratory had not documented QA activities since patient testing started in October of 2020. The TC agreed staff should have had a procedure to follow, so they could have performed and documented QA activities.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems

	identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory staff, the laboratory failed to ensure a procedure had been established so staff knew how to properly perform and document quality assurance (QA) activities taken for postanalytical laboratory systems for 6 of 6 months reviewed (October 2020 to March 15, 2021). Findings include: 1. Review of the laboratory's policies and procedures revealed: *Patient testing had begun on 10/9/20. *There was no policy or procedure for the completion and documentation of postanalytical QA activities. *No QA activities had been documented to ensure the patient specimen test results were accurate since patient testing had started. Interview on 3/15/21 during the survey with the laboratory's technical consultant (TC) and laboratory staff B revealed the laboratory had not written step-by-step procedures for the performance and documentation of postanalytical QA activities. The laboratory had not documented any QA activities since patient testing started in October of 2020. The TC agreed staff should have had a procedure to follow, so they could have performed and documented QA activities.