Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D1094231	09/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Senate Street Surgery Center	1801 Senate Blvd, Suite D1450, Indianapolis, IN	

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
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 and interview, the laboratory failed to retain maintenance records for the i-Stat analyzer (Abbott i-Stat 1 Testing System) from January to December 2021. Findings included: Review of Procedure: Point of Care Various Measurements by Abbott i-Stat 1 Testing System stated, "F. CLEANING AND/OR DISINFECTING THE ANALYZER 1. Cleaning is required when the analyzer has visible organic material present. 2. Disinfecting is required after every use, if the analyzer is shared between patients." The procedure was signed by the laboratory director on 6/16/2022. Review of 2021 i-Stat maintenance records revealed no written documentation of maintenance for the i-Stat in 2021. Review of the Record Retention Policy revealed there was no written documentation on retaining instrument maintenance records for two years. Review of CMS-116 revealed annual test volume for i-stat 1 testing system is 588. During an interview on 9/21/2022 at 12:29 PM with SP3 (Technical Consultant), they confirmed the i-stat maintenance records for 2021 could not be located.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if

	applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to record the room temperatures of the lab area for i-Stat - controls and reagent stored outside of refrigeration from 1/01/2022-9/21/2022. Findings Included: A tour of the laboratory on 9/21/2022 at 9:40 AM, revealed I-stat Level 1 (lot 321151) and Level 2 (321146) tricontrols and CHEM 8+ cartridges (lot H22159) stored outside of refrigeration on the counter and stored in a drawer Review of i-STAT CHEM8+ Cartridge Intended for instructions US only stated Storage Conditions: -Refrigeration at 2 to 8 Celsius (C) (35 to 46 Fahrenheit (F)) until expiration date. -Room Temperature at 18-30 C (64-86 F). Recommended shelf life is 14 days. Review of 2022 Temperature Records revealed the laboratory room temperatures were not recorded from 1/01/2022-9/21 /2022 where the i-stat tricontrols and CHEM8+ cartridges which held at room temperature. Review of CMS-116 revealed annual test volume for i-stat 1 testing system is 588. During an interview on 6/21/2022 at 12:29 PM, SP5 (Admin. Director) confirmed room temperature of the laboratory was not monitored where the i-Stat - controls and cartridges were stored at room temperature from 1/01/2022-9/21/2022.