Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0406780	05/04/2021
Name of Provider or Supplier	**Street Address, City, State**	
Brookings Health System	300 22nd Avenue, Brookings, 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 5/3/2021 through 5/4/2021. The Brookings Health System laboratory was found not in compliance with the following requirement: D5435 and D5445
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: D5435 Based on observation, interview, and record review the laboratory failed to retain the results of the daily background checks on the Sysmex XN-1000 analyzer for 15 of 28 months 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 5/4/21 at 10:20 a.m. of the Sysmex XN-1000 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 daily background check was dated 4/9/20. * Daily background counts prior to 4/9/20 were unavailable. *There was no way to verify if the background counts prior to 4/9/20 had been acceptable. *Increased background counts could lead to inaccurate patient specimen test results. Review of the annual test volume form revealed 10,178 hematology patient test specimens had been reported in 2019. Interview with the

	laboratory manager on 5/4/21 at 10:20 a.m. revealed: *She believed the XN-1000 was installed in late 2018. *She verified daily background counts had not been printed out or maintained. *She believed the Sysmex XN-1000 hematology analyzer's memory was sufficient to maintain the required 2 years of background counts. *No other log or spreadsheet was available to document the daily background test results.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interview, observation, and record review the laboratory failed to run external quality control (QC) at the manufacturer's minimum required frequency for one of one test test methods (Profile-V Medtox Scan Drugs of Abuse Test System) reviewed. Failure to run QC at the manufacturer's minimum required number and frequency could result in inaccurate patient test results having been reported. Findings include: 1. Observation and review of the laboratory's "Quality Control Plan (QCP) for Kit Testing" at 9:40 a.m. revealed: *The laboratory had developed an individualized quality control plan (IQCP). *The Profile-V Medtox Scan Drugs of Abuse Test System had been included in the laboratory's kit testing IQCP. *The IQCP stated, "External QC: 2 levels will be performed each month and with each new lot and shipment and recorded. 2 levels will be performed if the testing results seem questionable." Review of the Profile-V Medtox Scan Drugs of Abuse Test System manufacturer's package insert at 9:45 a.m. revealed, "You should run external controls routinely or as needed for any of the following reasons: (1) to practice the test with a known control, (2) when you open a new lot of devices, (3) once a week, (4) if you suspect that the reader or test device is not working properly, (5) if you have had a repeated unexpected test result or (6) if you suspect that the test devices have been stored improperly." Review of the annual test volume form revealed: *The test volumes reported were taken from 2019. *The laboratory performed approximately 295 urine drugs of abuse panels in 2019. Interview on 5/4/21 at 9:45 a.m. with the laboratory manager revealed: *She stated she reported the testing volumes for 2019 as the 2020 testing volumes had been skewed lower due to the Corona virus pandemic. *She believed performance of 2 levels of external QC only once a month had been required. *She confirmed the Profile-V Medtox Scan Drugs of Abuse package insert stated QC was required to be performed at a minimum of once a week.