Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0407323	05/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Prairie Lakes Healthcare System	401 9th Avenue Northwest, Watertown, 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 5/18/22 through 5/19/22. The Prairie Lakes Healthcare System laboratory was found not in compliance with the following requirement: D5445.
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 record review and interview, 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 Med Tox Scan Drugs of Abuse Test System) reviewed. Failure to run QC at the manufacturer's minimum required number and frequency could result in inaccurate reporting of patient results. Findings include: 1. Review on 5/18/22 at 1:45 p.m. of the laboratory's Med Tox Profile-V Scan individual quality control plan (IQCP) revealed the policy stated, "Two levels of external QC will be performed every 30 days and/or when a new box is opened whichever comes first." Review on 5/18/22 at 3:40 p.m. of the Profile-V Med Tox Scan Reader System Quick Reference Instructions, last revised June 2021, 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 laboratory had reported 508 urine drugs of abuse panels on patient specimens in 2021. Interview on 5/18/22 at 3:40 p.m. with serology section head A revealed: *The laboratory followed the Med Tox Profile-V IQCP. *The laboratory had performed QC on a monthly basis. *She was not aware the manufacturer had required two levels of QC to be performed at a minimum of once a week. *The Profile-V Med Tox Scan Reader System Quick Reference Instructions stated two levels of QC had been required to be performed at a minimum of once a week. Interview on 5/19/22 at 8:15 a.m. laboratory technical consultant B revealed: *QC had been run weekly prior to the development of the IQCP. *The IQCP had been put into use on 8/4/20. *She reviewed the IQCP monthly. *She believed performance of two levels of external QC once a month had been the minimum required.