

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  43D0658923	<b>(X3) Date Survey Completed</b>  08/27/2024
<b>Name of Provider or Supplier</b>  Avera St Benedict Health Center	<b>Street Address, City, State</b>  401 West Glynn Drive, Parkston, SD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 8/27/24. Avera St Benedict Health Center laboratory was found not in compliance with the following requirements: D5445.
<b>D5445</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform two levels of external controls each day of patient testing or establish an equivalent quality control (QC) method to verify the accuracy of one of one non-waived test (Profile-V Med Tox Scan Drugs of Abuse Test System) reviewed. Failure to run external QC could result in inaccurate reporting of patient results. Findings include: 1. Review on 8/27/24 at 11:30 a.m. of the laboratory's August 2024 urine drug screen log sheet revealed: *Two external QC levels had been reported on 8/7/24, 8/14/24, and 8/21/24. All external QC had been within acceptable limits. *Two patient specimens had been reported on 8/1/24 (424258 and 415756). *One patient specimen had been reported on 8/6/24 (485391). *One patient specimen had been reported on 8/12/24 (619095). *Two patient specimens had been reported on 8/20/24 (803080 and 814821). *There was no documentation external QC had been processed on the days patient specimens had been processed. Review of the Profile-V Med Tox Scan Reader System Quick</p>

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 approximately 45 urine drugs of abuse panels on patient specimens in 2023. Interview on 8/27/24 at 11:30 a.m. with lead technologist A revealed: \*She confirmed the laboratory performed external QC on the urine drug screen kit on a weekly basis. \*She confirmed the laboratory did not have an Individual Quality Control Plan (equivalent QA plan) that would have allowed the laboratory to perform external QC less frequently than each day of patient testing. \*She stated that external QC had been run each day of testing originally. The laboratory's procedure stated external QC could be done daily or weekly. The laboratory had switched to running external QC weekly due to the increased number of patient tests. \*She could not remember when the laboratory had switched from day of patient testing to processing external QC weekly.