Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385321	02/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Siouxland Urology Associates	455 Sioux Point Road, Dakota Dunes, 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 2/15/22 through 2/16/22. The Siouxland Urology Associates laboratory was found not in compliance with the following requirements: D5221.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure proficiency testing (PT) results had been reviewed, evaluated, and those activities documented for one of six PT events reviewed (Medical Laboratory Evaluation 2021 MLE-M2) to ensure the accurate identification of bacterial isolates grown from patient specimens cultures. Appropriate identification of a bacterial isolate is necessary to ensure the patient receives the appropriate antibiotic treatment. Findings include: 1. Review of the PT records revealed: *The laboratory subscribed to Medical Laboratory Evaluation for PT. *The subspecialty of Bacteriology - Urine Culture received a score of 83%, -Specimen UC-7 was marked unacceptable. -Specimen UC-7 had been reported as Enterococcus species. -Acceptable responses had included Corynebacterium urealyticum and Streptococcus salivarius. *Review of the laboratory's PT report revealed there had been no investigation of the unacceptable results. *No other documentation was provided of evaluation of the unacceptable PT results. Review of the laboratory's test volume form revealed 494 bacterial identification panels had been reported on patient urine culture specimens in 2021. Interview on 2/16/22 at 11:15 a.m. with laboratory personnel A revealed: *He confirmed there was no documentation the unacceptable PT result had been reviewed. *He did not know why an investigation had not been documented.