

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0385321	(X3) Date Survey Completed 07/11/2023
Name of Provider or Supplier Siouxland Urology Associates	Street Address, City, State 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 7/11/23. Siouxland Urology Associates laboratory was found not in compliance with the following requirements: D2009 and D5775.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure the laboratory director, or their designee, and testing personnel had signed the attestation statements for four of five American Association of Bioanalysts (AAB-MLE) proficiency testing (PT) events reviewed (AAB-MLE 2022 1st and 2nd testing events and 2023 1st and 2nd testing events). The attestation statements confirmed the PT samples had been tested in the same manner as patient specimens. Findings include: 1. Review on 7/11/23 at 8:15 a.m. of the 2022 and 2023 completed AAB-MLE PT testing event documentation revealed: *The laboratory participated in PT through AAB-MLE. *Each testing event included chemistry, non-chemistry and provider performed microscopy modules. *The following testing event attestation statements had not been signed: a. The 2022 first testing event had not been signed by the laboratory director or the testing personnel who had performed the testing. b. The 2022 second testing event had not been signed by the laboratory director or the testing personnel who had performed the testing. c. The 2023 first testing event had not been signed by the laboratory director or the testing personnel who had performed the testing. d. The 2023 second testing event had not been signed by the testing personnel who had performed the testing. On 7/11/23 at 1:00 p.m., a request had been made for a copy of the laboratory's proficiency testing policy. No policy was received for review.</p>

Interview on 7/11/23 at 1:00 p.m. with testing personnel A revealed: *He was not aware of any policies or procedures specific for proficiency testing. *He performed and reported the chemistry and non-chemistry testing modules. *One of the facility's providers performed and reported the provider performed microscopy module. *He confirmed the attestation statements had not been signed by the appropriate personnel. *He had been aware the attestation statements needed to be signed.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to establish and monitor criteria for acceptable differences between two of two analytes (calcium and creatinine) performed by two different analyzers (Abaxis Piccolo versus Mindray BS-200). Those test methods had not been evaluated twice a year in 2022 and to date in 2023 to determine if their differences had been acceptable. Findings include: 1. Review of the laboratory's test menu revealed: *Patient specimen requests for basic and complete metabolic chemistry panels had been performed on the Abaxis Piccolo. Basic and complete metabolic panels include calcium and creatinine analytes. *Patient specimen requests for calcium and/or creatinine only had been performed on the Mindray BS-200. Review of the annual test volume form revealed the laboratory had reported 244 patient calcium and 565 patient creatinine test specimens in 2023 from the Mindray BS-200. Test volumes for testing on the Abaxis Piccolo had not been available at the time of the survey. Review of the laboratory's quality assessment records revealed no documentation regarding a comparison of calcium and creatinine test methods had been completed in 2022 or to date in 2023. Review of the laboratory's 2/14/22 Quality Assurance policy revealed, "CLIA Standards for Quality Assurance- The fourth standard is a comparison of test results. If a laboratory has more than one test method of performing the same test, the laboratory must (twice a year) evaluate and define the relationship between the two methods (i.e. run the same specimen by each method and check for comparable results)." Interview on 7/11/23 at 1:00 p.m. with laboratory staff A revealed: *The laboratory performed calcium and creatinine patient specimen testing on the Abaxis Piccolo and the Mindray BS-200. *He confirmed comparison testing between the Abaxis Piccolo and the Mindray BS-200 had not been performed in 2022 or to date in 2023. *He had been aware that twice a year comparison testing was required for analytes processed on two different analyzers.