

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0385321	<b>(X3) Date Survey Completed</b>  09/04/2025
<b>Name of Provider or Supplier</b>  Siouxland Urology Associates	<b>Street Address, City, State</b>  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.		

<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 9/4/25. The Siouxland Urology Associates laboratory was found not in compliance with these requirement(s): 6018
<b>D6018</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</p> <p>(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure proficiency testing (PT) results had been reviewed, evaluated, and those activities documented for four of five 2024 and 2025 American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT events reviewed (provider performed microscopy 1st, 2nd and 3rd 2024 testing events and 1st 2025 testing event). PT samples are tested in the same manner as patient specimens and the evaluation of the PT testing results would ensure the accuracy of the patient specimen results. Findings include: 1. Review on 9/4/25 of the completed AAB-MLE 2024 and 2025 PT event records revealed: *The evaluation of corrective action documentation was absent from the following PT events: a. 2024 provider performed microscopy (PPM) 1st testing event -Fern testing was graded a score of zero. b. 2024 PPM 2nd testing event -Nasal Eosinophils were graded a score of zero. c. 2024 PPM 3rd testing event -Fecal Leukocytes were graded a score of zero. d. 2025 PPM 1st testing event -Nasal Eosinophils were graded a score of zero. Review on 9/4/25 of the laboratory's PT policy, last reviewed on 9/2/25, revealed: *"All PT results, as well as corrective actions, should be recorded and the records should be maintained for an appropriate period of time". Interview on 9/4/25 at 10:30 a.m. with testing personnel A revealed: *He was unaware that the PPM PT testing needed to have corrective action</p>

documented. \*They had not reviewed the results with the providers who completed the PPM PT testing. Interview on 9/4/25 at 12:00 p.m. with laboratory director B revealed: \*She confirmed corrective actions had not been documented for the PPM testing events. \*She confirmed that she had not reviewed the incorrect results with the personnel who performed the PT testing.