

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 43D0041454	<b>(X3) Date Survey Completed</b> 12/05/2023
<b>Name of Provider or Supplier</b> Flandreau Santee Sioux Tribal Clinic	<b>Street Address, City, State</b> 403 West Broad Avenue, Flandreau, 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 12/5/23. Flandreau Santee Sioux Tribal Clinic laboratory was found not in compliance with the following requirements: D2015.
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain a copy of required documentation related to the processing of 17 of 17 proficiency testing (PT) events reviewed (2022 Chemistry Core 1st, 2nd, and 3rd events; 2022 Immunology /Immunochemistry 1st, 2nd, and 3rd events; 2022 Hematology/Coagulation 1st, 2nd, and 3rd events; 2023 Chemistry Core 1st, 2nd, and 3rd events; 2023 Immunology /Immunochemistry 1st and 2nd events; 2023 Hematology/Coagulation 1st, 2nd, and 3rd events). That documentation would ensure the results submitted for evaluation had been the results submitted by the laboratory processing the PT samples. Findings Include: 1. Review on 12/5/23 of the laboratory's 2022 and 2023 American Proficiency Institute (API) PT event records revealed: *The laboratory subscribed to PT events through API. *PT specimens were processed, and the results submitted</p>

electronically via the company's website upon completion of testing. \*The laboratory had the ability to print a copy of the final PT results submitted for evaluation. \*The laboratory had not retained copies of final electronically submitted results for evaluation for the following events: -2022 API Chemistry Core 1st, 2nd, and 3rd testing events. -2022 API Immunology/Immunochemistry 1st, 2nd, and 3rd testing events. -2022 API Hematology/Coagulation 1st, 2nd, and 3rd testing events. -2023 API Chemistry Core 1st, 2nd, and 3rd events. -2023 API Immunology/Immunochemistry 1st and 2nd events. -2023 Hematology/Coagulation 1st, 2nd, and 3rd events. Interview on 12/5/23 at 10:45 a.m. with the laboratory supervisor revealed she confirmed: \*PT results were submitted electronically after PT samples had been processed. \*The laboratory had not printed copies of all final submitted results. Review of the laboratory's PT policy, effective 12/8/21 revealed: \*If results were submitted electronically, a copy of the submitted results should be retained. \*All PT records that are kept are to be made available for inspection by the surveyor.