

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0041454	(X3) Date Survey Completed 04/21/2022
Name of Provider or Supplier Flandreau Santee Sioux Tribal Clinic	Street Address, City, State 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.		

(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 4/21/22. The Flandreau Santee Sioux Tribal Clinic laboratory was found not in compliance with the following requirements: D5209 and D6028.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the review of laboratory records and interview the laboratory failed to establish written policies and procedures to assess the competency of testing personnel to perform preanalytical, analytical and post-analytical tasks in 2020, 2021, and to the date of the survey on 4/21/22. Findings include: 1. Review of the laboratory records revealed competency assessments had been performed for testing personnel in 2020 and 2021. A copy of the laboratory's competency assessment policy was requested on 4/21/22 at 11:20 a.m. The laboratory staff was unable to provide a copy of this policy. Interview on 4/21/22 at 11:20 a.m. with laboratory personnel A revealed: *She did not think the laboratory had a written procedure for competency assessment. *She was not aware the laboratory needed to have a written policy as the competency assessments had been completed on a yearly basis. The laboratory director was unavailable for interview at the time of the survey.</p>
D6028	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory director failed to ensure competency evaluations for one of two laboratory staff (B) were completed by qualified personnel (their credentials had not been reviewed to determine if they were qualified to serve as technical consultants) for the nonwaived test methods they had been performing under the laboratory's certificate. Findings include: 1. Review of the employee's file for laboratory staff B revealed her competency assessments were completed on 10/1/20, 3/18/21, and 9/12/21 had been performed by laboratory staff A. There was no indication the laboratory director was involved in the competency assessment process nor had he dated the evaluations. Review of the CMS 209 Laboratory Personnel Report Form signed by the laboratory director on 4/19/22 revealed the laboratory director was also serving as the technical consultant. Laboratory staff A and B were listed only as testing personnel and not listed as technical consultants. A copy of the laboratory's competency assessment policy was requested on 4/21/22 at 11:20 a.m. Laboratory staff A was unable to provide the requested copy. She did not think the laboratory had a competency assessment policy. Interview on 4/21/22 at 11:20 a.m. with laboratory staff A revealed: *She confirmed she had completed laboratory staff B's competency assessments. *She had an associate degree in medical technology. *She was not aware she did not qualify under the CLIA regulations as a technical consultant. The laboratory director was unavailable for interview at the time of the survey.