

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0658924	(X3) Date Survey Completed 12/04/2024
Name of Provider or Supplier Platte Health Center Avera	Street Address, City, State 601 East 7th, Platte, 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 12/4/24. Platte Health Center Avera laboratory was found not in compliance with the following requirements: D5209 and D6125
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 record review and interview the laboratory failed to establish written policies and procedures to assess the competency of laboratory personnel to perform preanalytical, analytical and post-analytical tasks in 2023 and 2024 through the date of the survey on 12/4/24. Findings Include: 1. Review of the laboratory records revealed competency assessments had been performed for testing personnel in 2023 and 2024. A copy of the laboratory's competency assessment policy was requested on 12/4/24 at 10:40 a.m. The laboratory staff was unable to provide a copy of the policy. Interview on 12/4/24 at 10:45 a.m. with technical supervisor A revealed: *She did not think the laboratory had a written policy for competency assessment. *She was not aware a written competency assessment policy was required, since they performed competencies for testing personnel on a yearly basis.</p>
D6125	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p>

This STANDARD is not met as evidenced by:

Based on record review and interview, the technical supervisors failed to assess competency through the testing of blind samples or external proficiency samples on all testing platforms for three of five laboratory personnel (C, D, E) in 2023 and 2024. Assessment of blind testing and/or external proficiency testing (PT) helps ensure competency of staff reporting patient test results. Findings include: Review on 12/4/24 at 9:30 a.m. of the laboratory staff's annual competency assessment records revealed: *Technical supervisor C had: - Annual competency evaluations on 12/27/23 and 12/2/24. -Not completed blind sample testing or PT samples for the departments of hematology and coagulation in 2023 and microbiology in 2024. -Performed patient testing in the departments of hematology, coagulation and microbiology during 2023 and 2024. *Testing personnel D had: -Annual competency evaluations on 12/18/23 and 12/2/24. -Not completed blind sample testing or PT samples for the department of immunohematology in 2023. -Performed patient testing in the department of immunohematology in 2023. *Technical supervisor E had: -Annual competency evaluations on 11/27/23 and 11/8/24. -Not completed blind sample testing or PT samples for the departments of immunohematology in 2023 and hematology and coagulation in 2024. -Performed patient testing in the departments of immunohematology, hematology and coagulation during 2023 and 2024. A copy of the laboratory's competency assessment policy was requested on 12/4/24 at 10:40 a.m. The laboratory staff was unable to provide a copy of this policy. Interview on 12/4/24 at 10:45 a.m. with Technical Supervisor A revealed: *She confirmed that technical supervisors B, C, E and herself had been involved with the competency assessment process. *She confirmed that laboratory staff C, D, and E had processed patient specimens in all testing departments within the laboratory. *PT events were rotated between staff, but there were only two to three PT events per year. *She had not been aware that blind testing or external proficiency testing was required for competency assessment in all departments within the laboratory annually. *The laboratory did not have a policy for performing competency assessments.