

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407818	(X3) Date Survey Completed 11/06/2024
Name of Provider or Supplier Mobridge Regional Hospital	Street Address, City, State 1401 10th Ave West, Mobridge, 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 11/6/24. Mobridge Regional Hospital laboratory was found not in compliance with the following requirements: D6125
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> <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 five of five testing personnel (A, B, C, D and E) in 2024. Assessment of blind testing and/or external proficiency testing (PT) helps ensure competency of staff reporting patient test results. Findings include: 1.Review on 11/6 /24 at 12:00 p.m. of the laboratory staff's annual competency assessment records revealed: *Technical supervisor A's annual competency evaluation had been completed on 2/5/24. -No blind sample testing or PT events had been documented for the departments of immunohematology, microbiology, hematology and coagulation. - Technical supervisor A had performed testing in immunohematology, microbiology, hematology and coagulation. *Technical supervisor B's annual competency evaluation had been completed on 2/20/24. -No blind sample testing or PT events had been documented for urinalysis. -Technical supervisor B had performed urinalysis testing. *Testing personnel C's annual competency evaluation had been completed on 2/6/24. - No blind sample testing or PT events had been documented for urinalysis. -Testing personnel C had performed urinalysis testing. *Testing personnel D's annual competency evaluation had been completed on 2/15/24. -No blind sample testing or PT events had been documented for coagulation. -Testing personnel D had performed</p>

coagulation testing. *Testing personnel E's annual competency evaluation had been completed on 2/25/24. -No blind sample testing or PT events had been documented for the departments of immunohematology, chemistry, urinalysis and hematology. - Testing personnel E had performed testing in immunohematology, chemistry, urinalysis and hematology. Review on 11/6/24 of the competency assessment policy last revised 11/24 revealed: *The following six procedures were required for assessment of competency for all personnel performing laboratory testing: -Direct observation of routine patient test performance. -Monitor the recording and reporting of test results. -Review of intermediate test results or worksheets, quality control records, PT testing and preventative maintenance records. -Direct observation of instrument maintenance and function checks. -Assessment of test performance through testing of previously analyzed specimens, internal blind testing, or external proficiency testing. -Assessment of problem-solving skills. Interview on 11/6/24 at 1:00 with technical supervisor B revealed: *She confirmed she had completed the 2024 annual competency assessments for testing personnel C, D, E and technical supervisor A. *She confirmed testing personnel A, B, C, D and E all had processed patient specimens on all testing areas within the laboratory. *PT events were rotated between staff. There were only two to three PT events each year and staff complete each PT event every other year. *She had not been aware that blind testing or external PT testing was required for competency assessment in all areas within the laboratory annually. Interview on 11/6/24 at 2:00 with technical supervisor A revealed: *She confirmed she had completed the 2024 annual competency assessment for technical supervisor B. *She confirmed annual competency assessments had not included blind testing or external proficiency for all areas in the lab.