

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 43D0407454	<b>(X3) Date Survey Completed</b> 08/28/2024
<b>Name of Provider or Supplier</b> Douglas County Memorial Hospital	<b>Street Address, City, State</b> 708 8th Street, Armour, 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 8/28/24. Douglas County Memorial Hospital laboratory was found not in compliance with the following requirements: D6120 and D6125.
<b>D6120</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, technical supervisor A failed to ensure that one of five laboratory personnel (laboratory supervisor B) had received a competency evaluation in 2023 for the test methods they had performed under the laboratory's certificate. Competency assessment verifies testing personnel were competent to correctly process patient specimens and to ensure the accuracy of the patient specimen results reported. Findings include: 1. Review on 8/28/24 at 8:40 am. of the employee competency records revealed: *Laboratory supervisor B had not had an annual competency evaluation documented in 2023. *A request was made to laboratory supervisor B for any additional documentation of an annual competency assessment completed for 2023. *No additional documentation was provided during the survey. Review of the CMS 209 Laboratory Personnel Form revealed laboratory supervisor B had been listed as the general supervisor. Review of the laboratory's delegation of duties revealed: * Technical Supervisor for High Complexity Testing *Responsibilities (High Complexity)... "h) Evaluating the competency of all testing</p>

personnel and perform test procedures, and report results promptly, accurately, and proficiently." Interview on 8/28/24 at 8:40 a.m. with laboratory supervisor B revealed: \*She confirmed she had not had a competency assessment in 2023. \*She confirmed that she had worked in all areas of the laboratory processing and reporting patient specimens. \*She was aware a yearly competency had been required.

**D6125**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(8)(v)

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.

This STANDARD is not met as evidenced by:

Based on record review and interview, the technical supervisor failed to assess competency through the testing of blind samples or external proficiency samples on all testing platforms for four of four testing personnel (testing personnel C, D, E and F) in 2023. Assessment of blind testing of specimens and/or external proficiency testing (PT) helps ensure competency of staff reporting patient test reports. Findings include: 1. Review on 8/28/24 at 8:40 a.m. of the laboratory staff's annual competency assessment records revealed: \*Testing personnel C's 2023 annual competency evaluation had been completed on 11/4/23. -"No PT events 2023" had been documented for blind testing in the areas of hematology, urinalysis, microbiology, serology, and arterial blood gas testing. \*Testing personnel D's 2023 annual competency evaluation had been completed on 11/4/23. -"No PT events 2023" had been documented for hematology, coagulation, urinalysis, and arterial blood gas testing. \*Testing personnel E's 2023 annual competency evaluation had been completed on 11/3/23. -"No PT events 2023" had been documented for serology, blood banking, arterial blood gas, and nucleic acid BioFire Torch RP2.1 and GI panel testing. -There had been no documentation of blind specimen testing in the area of urinalysis. \*Testing personnel F's 2023 annual competency evaluation had been completed on 11/3/23. -"No PT events 2023" had been documented for nucleic acid BioFire Torch RP2.1 and GI panel blind specimen processing. -There had been no documentation of blind testing in the areas of hematology, urinalysis, microbiology, serology, and arterial blood gas testing. Review 8/28/24 of the laboratory's undated Delegation of Duties revealed: \*Technical Supervisor for High Complexity Testing \*Responsibilities (High Complexity)... "h) Evaluating the competency of all testing personnel and perform test procedures, and report results promptly, accurately, and proficiently. The procedures for the evaluation of competency of the staff must include, but not limited too... (v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples." Interview on 8/28/24 at 08:40 a.m. with laboratory supervisor B revealed: \*She confirmed she had completed the 2023 annual competency assessments for testing personnel C, D, E, and F. \*She confirmed testing personnel C, D, E, and F processed patient specimens on all testing platforms within the laboratory. \*She confirmed she had not documented blind sample testing or external proficiency sample testing for all testing platforms in the laboratory for all testing personnel. \*PT events were rotated between staff. There were only 2-3 PT events each year for each testing platform. \*She had not been aware that specimen types other than PT samples had been acceptable to be used for blind specimen testing to ensure staff competency processing and reporting patient specimens.