

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 43D0658932	<b>(X3) Date Survey Completed</b> 03/15/2022
<b>Name of Provider or Supplier</b> Marshall County Healthcare Center	<b>Street Address, City, State</b> 413 9th Street, Britton, 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 3/15/22. The Marshall County Healthcare Center laboratory was found not in compliance with the following requirement: D5221.
<b>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure proficiency testing (PT) results had been reviewed, evaluated, and those activities documented for five of thirty-six PT events reviewed (College of American Pathologists [CAP] C-A 2020 General Chemistry Therapeutic Drugs, FH9-B 2021 Hematology Auto Differential, CM-B 2021 Clinical Microscopy, CGL-B 2021 Coagulation Limited, and FH9-C 2021 Hematology Auto Differential). Findings include: 1. Review of the 2020 CAP PT events revealed the following unacceptable test results: *C-A General Chemistry Therapeutic Drugs -Bilirubin Direct sample CHM-01 was graded as unacceptable. Review of the 2021 CAP PT events revealed the following unacceptable or ungraded test results: *FH-9 B Hematology Auto Differential -Blood cell identification sample BCP-11 was graded as unacceptable. -Blood cell identification sample BCP-13 was ungraded due to lack of participant or referee consensus. *CM-B Clinical Microscopy -Urine sediment identification sample CMP-14 was graded unacceptable. *CGL-B Coagulation Limited -Activated partial thromboplastin time sample CGL-8 was ungraded due to lack of participant or referee consensus. *FH9-C Hematology Auto Differential -Blood cell identification sample BCP-24 was ungraded due to lack of participant or referee consensus. Review of the laboratory's PT reports revealed there had been no investigation of unacceptable or ungraded results for the above listed samples. Review of the Laboratory Quality Assurance Program policy (written 1/20/14, last revised March 2021, and signed by</p>

the laboratory director on 3/10/22) revealed for: \*Proficiency Testing Performance - Verify documentation of investigation/corrective action taken on unacceptable proficiency testing (PT) results is done and reviewed by the laboratory director. - Verify all ungraded results are assessed for acceptability." \*Problem Investigation- Review, Documentation, Implementation of Corrective Action -If any QA [Quality Assurance] review indicates laboratory goals are not met and corrective action is needed, complete the Problem Investigation form including the following information: name of the investigator, the identified problem, date, explanation of the problem, suggested corrective action and resolution of the problem (including education of all involved employees), and date of implementing the corrective action. -Verify a follow-up monitor was done to ensure corrective action prevented re-occurrence. -If occurrences still happen, assess the situation again and implement further corrective action. -Did the corrective action take care of the problem?" Review of the laboratory's Problem Investigation forms revealed there had been no forms filed with regard to the failure to investigate and document any corrective action taken for the above listed PT reports. Interview on 3/15/22 at 10:20 a.m. with the lab manager revealed: \*She thought all unacceptable and ungraded samples had been reviewed. \*She confirmed there was no documentation the above samples had been reviewed.