

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0041615	(X3) Date Survey Completed 11/07/2023
Name of Provider or Supplier Bowdle Hospital	Street Address, City, State 8001 West Fifth St, Bowdle, 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 11/7/23. Bowdle Hospital laboratory was found not in compliance with the following requirements: D2015, D5435.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure specimen handling, preparation, and processing for proficiency testing (PT) had been documented for 38 of 40 PT events (College of American Pathologists [CAP] 2022 Cardiac Markers, Clinical Microscopy, Coagulation, Diagnostic Immunology, Hematology Automated Differential, and Transfusion Medicine A, B and C testing events; General Chemistry/Therapeutic Drugs B and C testing events; CAP 2023 Cardiac Markers, Clinical Microscopy, Coagulation, Hematology Automated Differential, General Chemistry/Therapeutic Drugs, Immunology, and Transfusion Medicine A, B and C testing events) reviewed. Findings include: 1. Review on 11/7/23 of the laboratory's 2022 CAP PT events revealed: *A completed External Proficiency Survey Flow Sheet documented the receipt, condition, and date of</p>

reconstitution for PT samples for the General Chemistry/Therapeutic Drugs and Transfusion Medicine A testing events. *Cardiac Markers, Clinical Microscopy, Coagulation, Diagnostic Immunology, Hematology Automated Differential A testing events had not had an External Proficiency Survey Flow Sheet completed. *Cardiac Markers, Clinical Microscopy, Coagulation, Diagnostic Immunology, Hematology Automated Differential, General Chemistry/Therapeutic Drugs, and Transfusion Medicine B and C testing events had not had an External Proficiency Survey Flow Sheet completed. Review of the lab's 2023 CAP PT events revealed the following had not had an External Proficiency Survey Flow Sheet completed: *Clinical Microscopy and Diagnostic Immunology A and B testing events. *Cardiac Markers, Coagulation, Hematology Automated Differential, General Chemistry/Therapeutic Drugs, and Transfusion Medicine A, B, and C testing events. Review on 11/7/23 of the laboratory's Handling Proficiency Testing Specimens procedure (last reviewed 1/28/21) revealed: *"1. Prepare an External Proficiency Survey Flow Sheet for this survey." *"12. Upon receipt of the survey evaluation form complete the rest of the flow sheet and take appropriate actions for all results outside of the stated criteria." Interview on 11/7/23 at 11:50 a.m. with the laboratory supervisor revealed: *She had started working in the laboratory in April 2022. *She was unaware of the External Proficiency Survey Flow Sheet. *She had not completed an External Proficiency Survey Flow Sheet for any PT testing event since she had begun working in the laboratory.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to calibrate the blood bank centrifuge to ensure proper centrifugation and accurate interpretation of the ABO Rh typing and crossmatch test methods. Findings include: 1. Review on 11/7/23 of the immunohematology maintenance records revealed the blood bank centrifuge had not been calibrated in 2022 or to date in 2023 to determine the combination of speed and timing of the blood bank centrifuge to ensure an optimum blood cell dot formation had been formed. That test method had been used as part of the ABO RH typing, antibody screening, and crossmatch procedures for determining patient blood type and compatibility with the donor blood units. Review of the annual test volume survey form revealed 16 ABO Rh blood types and 15 crossmatches had been performed on patient specimens during 2022. Interview on 11/7/23 at 12:10 p.m. with the laboratory supervisor revealed: *She had started working in the laboratory in April 2022. *She had not calibrated the blood bank centrifuge since she had begun work at the laboratory. *She had not been aware that the blood bank centrifuge should have been calibrated on a yearly basis.