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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>43D0041615 | <b>(X3) Date Survey Completed</b><br>01/05/2022 |
| <b>Name of Provider or Supplier</b><br>Bowdle Hospital   | <b>Street Address, City, State</b><br>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. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D0000</b>              | A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 1/5/22. The Bowdle Hospital laboratory was found not in compliance with the following requirement: D2009.   |
| <b>D2009</b>              | <p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b><br/>CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review and interview, the laboratory failed to ensure the laboratory director or their designee had signed the attestation statements of 36 of 42 College of American Pathology (CAP) proficiency testing (PT) surveys reviewed (CAP 2020 and 2021- Coagulation Limited CGL-A, CGL-B, and CGL-C; Hematology Automated Differential FH10-A, FH10-B, and FH10-C; General Chemistry Therapeutic Drugs C-A, C-B, and C-C; Cardiac Markers CAR-A, CAR-B, and CAR-C; Immunology S-A, S-B, and S-C; Clinical Microscopy CM-A, CM-B, and CM-C). The attestation statements confirmed the PT samples had been tested in the same manner as patient specimens. Findings include: 1. Review on 1/5/21 of the 2020 and 2021 completed CAP PT events revealed the following testing event attestation statements had not been signed by the laboratory director or their designee: *The 2020 Coagulation Limited CGL-A, CGL-B, and CGL-C. *The 2020 Hematology Automated Differential FH10-A, FH10-B, and FH10-C. *The 2020 General Chemistry Therapeutic Drugs C-A, C-B, and C-C. *The 2020 Cardiac Markers CAR-A, CAR-B, and CAR-C. *The 2020 Immunology S-A, S-B, and S-C. *The 2020 Clinical Microscopy CM-A, CM-B, and CM-C. *The 2021 Coagulation Limited CGL-A, CGL-B, and CGL-C. *The 2021 Hematology Automated Differential FH10-A, FH10-B, and FH10-C. *The 2021 General Chemistry Therapeutic Drugs C-A, C-B, and C-</p> |

C. \*The 2021 Cardiac Markers CAR-A, CAR-B, and CAR-C. \*The 2021 Immunology S-A, S-B, and S-C. \*The 2021 Clinical Microscopy CM-A, CM-B, and CM-C. Review on 1/5/21 at 2:10 p.m. of a letter signed by the current laboratory director (February 2021) and by the two previous laboratory directors delegated the duty of signing the PT attestation statements to the technical consultant. Interview on 1/5/21 at 2:10 p.m. with the general supervisor confirmed: \*The attestation statements had not been signed by the laboratory director or their designee. \*The technical consultant had been designated to sign the attestation statements by the laboratory director. \*She had not been aware the technical consultant had not signed the attestation statements on his regular monthly visits.