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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 43D0974321 | (X3) Date Survey Completed 12/17/2025 |
| Name of Provider or Supplier Brown Clinic - Northridge | Street Address, City, State 511 14th Avenue Ne, Watertown, 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 12/17/25. The Brown Clinic-Northridge laboratory was found not in compliance. |
| D2009 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) 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: Based on record review, policy review, and interview, the laboratory failed to ensure the laboratory director had signed the attestation statements for 25 of 25 proficiency testing (PT) events reviewed (American Proficiency Institute Chemistry Core 2024 1st, 2nd, and 3rd events and 2025 1st, 2nd, and 3rd events; Hematology/Coagulation 2024 1st, 2nd, and 3rd events and 2025 1st and 2nd events; Microbiology 2024 1st, 2nd, and 3rd events and 2025 1st and 2nd events; Immunology/Immunochemistry 2024 1st, 2nd, and 3rd events and 2025 1st and 2nd events; Chemistry Miscellaneous 2024 1st and 2nd events and 2025 1st and 2nd events). Findings include: 1. Review on 12/17/25 at 10:00 a.m. of the laboratory's 2024 and 2025 American Proficiency Institute (API) PT event records revealed the laboratory was subscribed to PT events through API. Technical consultant B had signed the attestation statements, but was not delegated this task by the laboratory director. The laboratory director had not signed the PT event attestation statements for the: -2024 Chemistry Core 1st event -2024 Chemistry Core 2nd event -2024 Chemistry Core 3rd event -2024 Hematology/Coagulation 1st event -2024 Hematology/Coagulation 2nd event -2024 Hematology/Coagulation 3rd event -2024 Microbiology 1st event -2024 Microbiology 2nd event -2024 Microbiology 3rd event -2024 Immunology/Immunochemistry 1st event -2024 Immunology/Immunochemistry 2nd event -2024 Immunology</p> |

/Immunohematology 3rd event -2024 Chemistry Miscellaneous 1st event -2024
Chemistry Miscellaneous 2nd event -2025 Chemistry Core 1st event -2025 Chemistry
Core 2nd event -2025 Chemistry Core 3rd event -2025 Hematology/Coagulation 1st
event -2025 Hematology/Coagulation 2nd event -2025 Microbiology 1st event -2025
Microbiology 2nd event -2025 Immunology/Immunohematology 1st event -2025
Immunology/Immunohematology 2nd event -2025 Chemistry Miscellaneous 1st event
-2025 Chemistry Miscellaneous 2nd event Review of the laboratory's PT policy, with
the effective date of June 2025, revealed, "the data submission forms must be signed
by the Laboratory Director". Interview on 12/17/25 at 11:30 a.m. with technical
consultant A revealed: a. She was not aware that the laboratory director needed to sign
the attestation statement forms. b. She thought that only the corrective action forms
needed to be signed. c. She confirmed that the laboratory director had not signed the
above attestation statement forms.