

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0408180	(X3) Date Survey Completed 10/27/2022
Name of Provider or Supplier Monument Health Wall Clinic	Street Address, City, State 112 7th Avenue, Wall, 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 10/27/22. Monument Health Wall Clinic laboratory was found not in compliance with the following requirement(s): D2009.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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: Based on record review and interview, the laboratory failed to ensure the laboratory director or their designee had signed the attestation statements of 5 of 6 American Proficiency Institutes (API) proficiency testing (PT) surveys reviewed (API 2021 2nd and 3rd Hematology/Coagulation events, 2022 1st and 2nd Hematology/Coagulation events, and the 2022 2nd Microbiology event). The attestation statements confirmed the PT samples had been tested in the same manner as patient specimens. Findings include: 1. Review on 10/27/22 at 9:30 a.m. of the 2021 and 2022 completed API PT events revealed the following testing event attestation statements had not been signed by the laboratory director or their designee: *The 2021 Hematology/Coagulation 2nd testing event *The 2021 Hematology/Coagulation 3rd testing event *The 2022 Hematology/Coagulation 1st testing event *The 2022 Hematology/Coagulation 2nd testing event *The 2022 Microbiology 2nd testing event Review on 10/27/22 at 10:20 a.m of the "Monument Health Wall Clinic Lab (WAC7A)" form, signed by the laboratory director on 4/22/21, delegated the duty of signing the PT attestation statements to (technical consultant's name). Review on 10/27/22 at 10:20 a.m of the 4 /20/21, 12/1/21, and 5/2/22 competency forms for the technical consultant completed and signed by the laboratory director revealed her duties included, "Signing the attestation that PT specimens were tested in the same manner as patient specimens."</p>

The signed forms indicated the technical consultant was competent to perform the job duties delegated to her. Review 10/27/22 at 10:30 a.m. of the 2021 and 2022 "Monument Health Wall Clinic Visit with (testing personnel A's name)" forms completed by the technical consultant after each quarterly visit revealed: *7/20/21- "Proficiency Testing ... Heme (hematology) 1st event 2021 (scored) 96% on Lymphs-instrument PM'd (preventative maintenance performed) and calibrated. (Scored) 0% on wet prep- reviewed the picture with staff." *11/9/21 - "Proficiency Testing... Heme 2nd event 2021 (scored). 100%." *2/8/22- "Proficiency Testing... Heme 3rd event 2021 (scored) 100%." *4/26/22- "Proficiency Testing... Heme 1st event 2021 (2022) (scored) 100%." *The technical consultant had not made a 3rd quarter visit to date. Interview on 10/27/22 at 10:20 a.m with testing personnel A revealed: *She confirmed the attestation statements had not been signed by the laboratory director or their designee. *She confirmed the technical consultant had been designated to sign the attestation statements by the laboratory director. *She gave the technical consultant the books to review and sign on her regular quarterly visits. *She had not been aware the technical consultant had not signed the attestation statements on her regular quarterly visits. *She stated, "(The technical consultant) is very new to the job. I should have verified she had signed all the paperwork."