Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407520	(X3) Date Survey Completed 07/09/2025
Name of Provider or Supplier Hrmc Physicians Clinic	**Street Address, City, State** 534 Oregon Southeast, Huron, 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 7/9/25. HRMC Physicians Clinic laboratory was found not in compliance with the following requirements: D5775 and D6053.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish and monitor criteria for acceptable differences between one analyte (human chorionic gonadotropin) hCG performed by two different test methods (qualitative vs quantitative). Those test methods had not been evaluated twice a year in 2024 and to date in 2025 to determine if their differences had been acceptable. Findings include: 1. Review of the laboratory's test menu revealed: * hCG qualitative patient specimen tests had been performed using Cardinal Health hCG combo kits. * hCG quantitative patient specimen tests had been performed on the Siemens EXL 200 analyzer. Review of the laboratory's annual test volume form revealed 7 patient serum qualitative hCG specimen tests and 185 patient serum quantitative hCG specimen tests were performed in 2025. Review of the laboratory's quality assessment records revealed there was no documentation that indicated a comparison of qualitative and quantitative hCG test methods had been completed in 2024 or to date in 2025. Interview on 7/9/25 at 1:00 p.m. with laboratory director C revealed: *The laboratory had performed hcG qualitative patient specimen testing with Cardinal Health serum test kits. *The laboratory had performed hCG quantitative patient specimen testing on the Siemens EXL 200 analyzer. *She confirmed comparison testing between the hCG

	qualitative and quantitative test methods had not been performed in 2024, nor to date in 2025. *She had been aware that, twice a year, comparison testing was required for analytes processed with two different test methods.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and interview, the technical consultant failed to ensure one of five laboratory personnel (testing personnel B) had received two competency assessments during their first year of patient testing for the test methods they had been performing. Competency assessment helps ensure staff can process and accurately report patient test specimens. Findings include: 1. Review on 7/9/25 at 11:25 a.m. of the laboratory's Centers for Medicare's Services 209 Laboratory Personnel Form signed by laboratory director C On 7/2/25, revealed laboratory staff B was listed as testing personnel. 2. Review on 7/9/25 at 11:30 a.m. of the laboratory's employee competency assessments for testing personnel B revealed: *He had started testing patient samples in May 2023. *He had his initial training orientation on 5/15/23. *His first competency assessment had been completed by technical consultant A on 3/12 /24. *His next competency assessment had been completed by technical consultant A on 4/17/25. Review on 7/9/25 at 12:00 p.m. of the laboratory's competency assessment procedure, last revised 12/24 revealed: *New employees would be evaluated after their initial orientation. *New employees would then be evaluated biannually during their first year of employment and annually after. Interview on 7/9 /25 at 12:15 with laboratory director C revealed: *She and technical consultant A had been cross-training staff between the clinic and the hospital. *Testing personnel B had previously only worked at the hospital. *She was aware that new staff needed to have two competency assessments, even if they were cross-training. *She confirmed a second competency had not been completed within testing personnel A's first year of patient testing.