Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410743	03/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Madison Valley Medical Center	305 North Main Street, Ennis, MT	

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
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. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on record review of 2019, 2020 instrument comparison documentation and interview with technical supervisor (TS) #1, the laboratory failed to perform instrument comparison for the analyzers, CoaguChek and Stago Start 4 for prothrombin two times a year. Findings: 1. Review of laboratory instrument comparison documentation showed the laboratory failed to perform and document comparison studies for the CoaguChek and Stago Start 4 analyzers performing prothrombin analyte testing for 2019 and 2020. 3. Interview with technical supervisor TS #1 on 3/15/2021 at 10:30 AM confirmed the laboratory failed to perform twice a year instrument comparison.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

	This STANDARD is not met as evidenced by: Based on review of 2019 competency records, Quality Assessment Plan for i-State Troponin, and interview, the technical supervisor (TS) #1 failed to perform annual competency assessment for 7 of 17 Testing Personnel (TP). Findings: 1. Review of personnel competency evaluations revealed that laboratory failed to provide proof of annual competency assessments for TP #1, TP #10, TP #13, TP #14, TP #15, TP #16, TP #17 for year 2019. 2. Review of laboratory procedure, Quality Assessment Plan for i-State Troponin revealed "9. A six-month competency review for new employees will be performed as well as an annual competency by the Laboratory manager on a direct observation method." 3. Interview with Technical Supervisor (TS) #1 on 3/15 /2021 at 11:00 AM confirmed the laboratory failed to perform 7 of 17 testing personnel competency assessments for year 2019.