Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410743	11/30/2022
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
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation, review of maintenance documentation, policy and procedures, and interview with technical supervisor (TS) #1 the laboratory failed to establish a procedure and perform function checks to verify the accuracy of one of one pipette used in the laboratory from January 1, 2021, to November 30, 2022. Findings: 1. Observed one 50 L Fisher Brand pipette in the laboratory available for use with no verification labels. 2. A review of laboratory maintenance records lacked documentation of annual verification checks for the pipette for years 2021 and 2022. 3. A review of policy and procedures lacked instruction to include the frequency and type of accuracy checks for the pipette. 4. An interview with the (TS) #1 on November 30, 2022, at 9:40 AM, stated the laboratory was not aware that the pipette needed to be verified for accuracy from January 1, 2021 to November 30, 2022
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--

	(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, laboratory policies and procedures, Individualized Quality Control Plan (IQCP) and interview with the Technical Supervisor (TS) #1, the laboratory failed to establish, follow, and perform external control at the frequency required by their procedure or manufacturer's instructions for Pro Advantage human chorionic gonadotropin (HCG) serum and urine kits, DCA Vantage Microalbumin and Creatinine and the Alere Triage D-dimer from January 1, 2021 to November 30, 2022. Findings: 1. A review of Pro Advantage package insert for the detection of HCG in urine and serum revealed the laboratory failed to follow manufacture's instructions as stated, "For urine testing, controls should be tested with each new lot or shipment of product, with each new operator, monthly as a check on continued storage conditions." 2. A review of Serology Worksheet for HGC QC records lacked an external positive and negative urine control for February, March, April, May, June, July, August, September, and October of 2022. 3. A review of Serum HCG IQCP revealed the laboratory failed to follow their procedure to perform external positive and negative serum controls "for each kit upon receipt of the kit." 4. A review of Serology Worksheet for HGC QC records lacked an external positive and negative check for a new HCG kit (lot number 1052044 exp date 5/31/2023) used to test 29 of 29 patients from June 18, 2022 to November 30, 2022 5. A review of IQCP for DCA Vantage Microalbumin/Creatinine revealed the laboratory failed to perform external controls as stated, "Two levels are run when the box arrives, and one level of control is run monthly thereafter." 6. A review of Microalbumin Creatinine Worksheet revealed the laboratory failed to perform one level of external control for microalbumin and one level of external control for creatinine for February, June, July, August, October, and November for 2021 and January, February, March, April, May, June, July, August, September, and October of 2022. 7. A review of Microalbumin Creatinine Worksheet revealed the laboratory failed to perform two levels of external controls for both creatinine and microalbumin for kit lot# 0463 expiration date 2-24 used to test 27 of 27 patients from July 12, 2022 to October 31, 2022 8. A review of DCA Vantage Operator's Guide revealed the lab failed to run quality control as stated, "each time a calibration card is scanned" and record results. No DCA Vantage calibration records were available for review. 9. A review of IQCP for the Alere Triage D-dimer revealed the laboratory failed to follow their procedure to perform external QC at the frequency defined, "Two levels are run when the box arrives, and one level of control is run monthly thereafter." 10. A review of Triage D-dimer QC revealed the laboratory failed to perform one level of external control for August, October, and December for the year 2021 and January, February, March, April, May, June, August and November of the year 2022. 11. An interview with the TS #1 on November 30, 2022, at 9:30 AM, confirmed the laboratory failed to establish, follow, and perform external qc at the frequency required by their, IQCP or manufacturer's instruction from January 1, 2021, through November 30, 2022 for the above listed platforms.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)

	(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of hematology records and interview with the technical supervisor (GS)#1, the laboratory failed to document the intended staining characteristics for each day manual differentials slides were stained from January 1, 2021 to November 30, 2022. Findings: 1. A review of hematology records revealed the laboratory failed to document the staining quality of manual differential slides each day that slides are stained for the years 2021 and 2022. 2.The hematology procedure lacked how the laboratory would document staining quality control checks for manual differentials slides. 3. An interview on November 30, 2022, at 11:30 AM with TS #1 confirmed the laboratory failed to document staining quality of manual differential slides from January 1, 2021 to November 30, 2022.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of quality control records, Individualized Quality Control Plan (IQCP), and interview with Technical Supervisor (TS) #1, the laboratory failed to include an ongoing mechanism to monitor, assess and correct problems in their IQCP's quality control plan to prevent the lack of quality controls (QC) performed for human chorionic gonadotropin (HCG), D-dimer, Microalbumin and Creatinine performed in the laboratory from January 1, 2021 to November 30, 2022. Findings: 1. The laboratory's Quality Control Plan for serum HCG, DCA Vantage Microalbumin and Creatinine and the Alere Triage D-dimer lacked instruction for ongoing mechanism to monitor, assess and correct problems. 2. No annual IQCP assessments were available for review. 3. A review of Serology Worksheet for HGC, Microalbumin Creatinine Worksheet and Triage D-dimer QC Records lacked review for quality assessment checks. 3. An interview with TS #1 on November 30, 2022, at 5:00PM, confirmed the laboratory failed to have included in their IQCP's quality control plan an ongoing mechanism to monitor, assess and correct problems and failed to perform quality assessments checks from January 1, 2021 to November 30, 2022.