Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0690353	03/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Western Montana Clinic Broadway Bldg	500 West Broadway, Missoula, 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 instrument comparison documentation and interview with Technical Supervisor (TS) #1 , the laboratory failed to perform instrument comparison for two BD Affirm MicroProbe processors for analytes bacterial vaginosis, vulvovaginal candidiasis and trichomoniasis two times a year from January 1, 2020 to March 16, of 2022. Findings: 1. Review of laboratory instrument comparison documentation showed the laboratory failed to perform comparison studies in unison using testing materials with known values (proficiency testing samples, split samples or "blind" samples) and define the relationship between results for two BD Affirm MicroProbe processors for analytes bacterial vaginosis, vulvovaginal candidiasis and trichomoniasis two times a year. 2. Interview with TS #1 on March 16, 2022 at 8:15 AM, confirmed the laboratory failed to perform in unison twice a year instrument comparison for two BD Affirm MicroProbe processors for analytes bacterial vaginosis, vulvovaginal candidiasis and trichomoniasis two times a year from January 1, 2020 to March 16, of 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 record review, procedures and interview with the technical supervisor (TS) #1, the laboratory failed to identify and correct problems to prevent recurrence and failed to document and monitor corrective actions. Findings: 1. Review of pipette verification data for 2020 and 2021 revealed the Blood Bank #A14406781 pipette, failed precision checks (coefficient of variation (CV)) on 8/10/2020 and 7/16/2021. 2. Review of Streck Pipette Verification procedure lacks information on what to do when the pipette fails to pass. 3. Review of centrifuge verification data for 2020 and 2021 revealed tachometer readings for LW Scientific U8V-1 #S105463 on 8/7/2020 was 1780 RPM and LW Scientific U8V-1 #V120774 on 10/1/2021 was 1792 RPM. 4. Review of Test Systems, Equipment, Instruments, Reagents, Materials, and Supplies procedure revealed "Acceptable tachometer ranges for WMC Centrifuges are: LW Scientific: 1800-1920 RPM for 5 Minutes" and "If not acceptable corrective action must be taken and documented" 5. No corrective action documents for the failures listed above were available for review. 6. An interview with the TS#1 on March 15, 2022 at 4:30 PM confirmed the laboratory failed to identify and correct problems to prevent recurrence and failed to document and monitor corrective actions for unacceptable checks of pipette and centrifuges.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review, procedures and interview with the technical supervisor (TS) # 1, the laboratory failed to ensure the original date and time of collection was documented on the final patient results report and ensure testing was completed within the specimen testing window. Findings: 1. Review of Coronavirus (COVID-19), NAAT patient results report ID#212920027NW revealed Collected and Received date and time as 10/19/2021 1335. 2. Review of Quality Assessment Plan procedure revealed, "Test Records ... Each tech randomly select samples and conducts an audit of the specimen labeling through proper report display in the EMR. This audit looks particularly at matching patient identification from written specimen labels, to attached specimen labels, to recorded date within the EMR: 1. Specimen ID, 2. Date and Time (Collection -Testing), 3. Resulting testing personnel, 4. Any associated instrument print-out, 5. Completed report (preliminary or corrected if applicable) and time of completion." 3. Interview with TS #1, on March 15, 2022 stated the collection date and time on the patient results report is when the packing list is received from WMC Now Care and can differ from the specimen label's collection date and time. 4. Review of Aptima SARS-CoV-2 product insert: Swab Specimen Collection states, "After collection, specimens collected in VTM/UTM can be stored at 2C to 8C up to 96 hours before transferring to the Specimen Lysis Tube" and "After collection, specimens in the Aptima Multitest Tube, the Hologic Direct Load Tube, and the

	Hologic Direct Load Capture Cap Tube, may be stored at 2C to 30C up to 6 days." 5. Laboratory documentation lacked information on monitoring original sample collection time to test completion duration.