Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0663007	04/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Central Montana Medical Center	408 Wendell Ave, Lewistown, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review, and interview with the General Supervisor (GS)#1, the laboratory failed to retain the quality control (QC) documentation for blood gases tests (pH, PCO2, PO2) performed on the OPTI CCA-TS2 Analyzer for years 2019 and 2020. Findings: 1. No QC documentation for blood gasses performed in 2019 and 2020 on the OPTI CCA-TS2 Analyzer were available for review. 2. Interview on April 27, 2021 4:00 PM with (GS)#1 confirmed the QC documentation for blood gases tests (pH, PCO2, PO2) performed on the OPTI CCA-TS2 Analyzer was not retained for years 2019 and 2020. .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation, review of maintenance records and interview with General Supervisor (GS)#1, the laboratory failed to recertify the Biosafety Cabinet located in the Microbiology Section for 2020. Findings: 1. Observed Microbiology Biosafety Cabinet's certification sticker had expired May of 2020. 2. No 2020 maintenance

	record for recertification of the Biosafety Cabinet was available for review. 3. Interview on April 27, 2021 2:30 PM with (GS)#1, confirmed the Biosafety Cabinet certification had expired as of May 2020. .
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 patient results reports, laboratory policies and interview with the general supervisor (GS)#1, the laboratory failed to have a system in place to verify patient result reports found in Cerner EHR System provided by Billings Clinic in Billings, MT, two times a year or after pertinent software upgrades for accuracy. Findings: 1. No verification documents of the Cerner EHR System were available for review. 2. Review of Accession # 20-318-2166 patient results report revealed the CBC Reference Range for HGB, Hct, and MPV differed from the references ranges listed in Policy No. Lab-HEM-001-20 reference ranges. 3. Review of Accession # 20-318-2166 patient results report revealed the Automated Differential reference ranges for Imm Grans%, Neut Abs, Lymph Abs, Mono Abs, Eos Abs, Baso abs, and Imm Grans Abs differed from the reference ranges values listed in Policy No. Lab-HEM-001-20. 4. Interview on April 27, 2021 9:13 AM with (GS)#1 stated the results report's reference values listed in Cerner EHR System are from their affiliate, Billings Clinic and had not been compared against Central Montana Medical Centers policies and laboratory's verified reference ranges twice a year or after pertinent software upgrades for accuracy.