

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0663007	(X3) Date Survey Completed 07/23/2024
Name of Provider or Supplier Central Montana Medical Center	Street Address, City, State 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	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and interview with Technical Supervisor (TS) #1, the laboratory failed to retain two years of records for their maintenance checks of four out of four centrifuges for the year 2022 and calibration documents for new lots of d-dimer and fibrinogen reagents for 2023. Findings: 1. A record review of maintenance function checks for four out of four centrifuges revealed the laboratory failed to retain 2022 records. 2. The laboratory lacked calibration records for 2023 for new lots of d-dimer and fibrinogen performed on the Stago Compact Max and Stago Satellite hematology analyzers. 3. An interview with TS #1 on July 23, 2024, at 9:30 AM confirmed that the laboratory failed to retain 2022 maintenance check records for their centrifuges and calibration records for new lots of d-dimer and fibrinogen reagents performed in 2023.</p>