

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0406030	(X3) Date Survey Completed 09/17/2024
Name of Provider or Supplier Centracare Richmond	Street Address, City, State 130 First St Ne, Richmond, MN	
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 observation, document review, and interview with laboratory personnel, the laboratory failed to retain Hematology quality control (QC) records from 2022 and 2023 for at least 2 years. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 9:05 a.m. on 09/13/24. 2. A Beckman Coulter DxH 520 hematology analyzer was observed as present and available for use during the tour of the laboratory. The laboratory implemented Complete Blood Count testing using this analyzer in November 2022. 3. Hematology QC testing with three levels of QC material was required daily as established in the Beckman Coulter DxH 520 procedure found in PolicyStat, the laboratory's policies and procedures software. 4. QC documentation from the time period reviewed, January through March 2023, was not found in laboratory records nor was this information retained in data available in the analyzer. The laboratory was given on opportunity to provide the missing documentation within five days of the survey. 5. In an interview at 9:50 a.m. on 09/13/24, the TC confirmed the above finding. 6. In an email received at 3:45 p.m. on 09/17/24, the laboratory director indicated the QC records from November 2022 through March 2023 could not be provided. .</p>