

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0406030	(X3) Date Survey Completed 10/06/2022
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
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure two levels of acceptable quality control (QC) results were obtained on one of sixty two days of quantitative Hematology testing in 2021. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:05 a. m. on 10/06/22. 2. An Abbott Cell-Dyn Emerald blood analyzer was observed as present and available for use during the tour of the laboratory. The laboratory performed Complete Blood Count (CBC) quantitative analysis using this analyzer. 3. The Emerald Procedure, found in the electronic procedure software PolicyStat, indicated testing with three levels of QC material was required each day of patient testing. 4. Cell-Dyn Emerald Quality Control reports indicated two levels of acceptable QC results were not obtained on one of sixty two days of testing in January through March 2021. See below. Date of testing: 02/17/21 Low control: three analytes out of range - Platelets - Mean Corpuscular Hemoglobin - Mean Corpuscular Hemoglobin Concentration Normal control: No record of testing High control: Acceptable 5. Six patient CBC test results were obtained on 02/17/21 as indicated on the Cell-Dyn Emerald History report. 6. In an interview at 1:25 p.m. on 10/06/22, the TC confirmed the above finding. .</p>