Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0927853	12/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Centracare - Becker Clinic	12800 Rolling Ridge Road, Becker, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure three of five reportable ranges obtained during the single Hematology performance verification (PV) activity completed in 2021 were adopted by the laboratory. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 10:05 a.m. on 12/12/22. 2. A Beckman Coulter DxH520 hematology analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began performing Complete Blood Counts (CBC's) with Automated Differential testing on this analyzer in May 2021. 3. PV activities on the DxH520 analyzer were completed in May 2021 as indicated in laboratory records found in the Performance Verification Data Manual DxH520. Five analytes were reviewed for reportable range accuracy as indicated below. WBC - White Blood Cells RBC - Red Blood Cells HGB - Hemoglobin PLT - Platelets HCT - Hematocrit 4. The upper reportable range limits adopted by the laboratory for HGB, PLT, and HCT did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated in the PV documents and the Performing Complete Blood Count with Differential on the DxH 520 Analyzer procedure located in the Laboratory Procedure Manual. See below. Analyte PV Procedure HGB 0-21.06 0.2-25.0 PLT 0.1-1967.8 7.0-

	2000.0 HCT 0.0-76.2 0.0-85.0 5. The laboratory performed approximately 10,374 Hematology tests annually as indicated on the Clinical Laboratory Improvement Amendments Application for Certification provided by the laboratory on 12/12/22. 6. In an interview at 1:15 p.m. on 12/12/22, the LD confirmed the above finding. .