

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405398	(X3) Date Survey Completed 12/02/2022
Name of Provider or Supplier Centracare-Willmar Lakeland Clinic	Street Address, City, State 502 2nd St Sw, Willmar, 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	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure one of one reportable range obtained during the single Hematology performance verification (PV) activity completed in 2021 was adopted by the laboratory. In addition, the laboratory failed to ensure two of five reportable ranges obtained during the single Hematology PV activity completed in 2022 were adopted by the laboratory. Findings are as follows: The laboratory performed Hematology testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory at 10:05 a.m. on 12/02/22. The laboratory performed approximately 40,520 Hematology tests annually as indicated on the Clinical Laboratory Improvements Amendments (CLIA) Application for Certification provided by the laboratory on date of survey. A. 2021 Polymedco Sedimat 15 Plus PV 1. A Polymedco Sedimat 15 Plus Automated ESR Reader was observed as present and available for use during the tour of the laboratory. The laboratory began performing Erythrocyte Sedimentation Rate (ESR) with this device on 04/13/21. 2. PV activities for ESR testing on the Sedimat 15 Plus were completed in April 2021 as indicated in laboratory records found in the Linearity & Verifications manual. 3. The upper and lower reportable range limits adopted by the laboratory for ESR did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated in</p>

the PV documents and the Sedimat 15 ESR procedure located in the Lab Procedure Manual. See below. Analyte PV Procedure ESR 2-77 0-140 4. In an interview at 2:45 p.m. on 12/02/22, TC1 confirmed the above finding and indicated there were no limits in the laboratory's information system (LIS) for this test. B. 2022 Beckman Coulter DxH 520 PV 1. A Beckman Coulter DxH 520 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 on 04/11/22. 2. PV activities for CBC testing on the DxH 520 analyzer were completed in March 2022 as indicated in laboratory records found in the Performance Verification Data Manual DxH 520. 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 3. The upper and /or lower reportable range limits adopted by the laboratory for HGB 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 Beckman Coulter DxH 520 procedure located in the Lab Procedure Manual. See below. Analyte PV Procedure HGB 0.01-19.2 0.5-25.0 HCT 6.9-71 0.0-85.0 4. In an interview at 2:40 p.m. on 12/02/22, TC1 confirmed the above finding and indicated the HGB LIS limit was 0.2-25.0 and there were no limits in the LIS for HCT. .

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

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--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform quality control (QC) activities as established in an Endocrinology Individualized Quality Control Plan (IQCP) for two of ten patient specimens tested in 2022. Findings are as follows: 1. The laboratory performed Endocrinology testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory at 10:05 a.m. on 12/02/22. 2. OSOM hCG Combo Test kits were observed as present and available for use during the tour. 3. Serum hCG QC performance using positive and negative control material was required monthly as established in the OSOM HCG Combo Test procedure and in the laboratory's IQCP for the test, both found in the Laboratory Procedure Manual. 4. The laboratory exceeded the monthly time interval for QC performance for two of ten patient specimens tested in 2022 as indicated in electronic laboratory reports generated on date of survey. See below. QC date Pt test date Days elapsed 05/24/22 07/22/22 60 05/24/22 07/25/22 63 5. In an interview at 2:20 p.m. on 12/02/22, TC1 confirmed the above finding.