Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405983	11/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Centracare Melrose	525 Main St W, Melrose, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to investigate two unacceptable Hematology proficiency testing (PT) results out of thirty challenges completed in 2021. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor during a tour of the laboratory at 8:10 a.m. on 11/09/22. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. The laboratory received one unacceptable Eosinophil % PT result of fifteen Eosinophil % testing challenges completed in 2021 and one unacceptable Monocyte % PT result of fifteen Monocyte % testing challenges completed in 2021 as indicated in API reports. See below. 2021 1st Hematology event Test: Eosinophil % Sample: PNT-01 Laboratory Result: 5.5 API expected range: 1.6-5.4 2021 1st Hematology event Test: Monocyte% Sample: PNT-03 Laboratory Result: 1.8 API expected range: 0.0-1.6 4. Investigation of unacceptable PT results was required as established in the laboratory's Proficiency Testing Policy located in Policystat, the laboratory's policy management software. 5. Investigation of the unacceptable PT results was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 6. In an interview at 10:50 a.m. on 11/09/22, the Technical Supervisor confirmed the above finding. .
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 two of five reviewed Hematology reportable ranges and two of two Chemistry reportable ranges obtained during two of three performance verification (PV) activities completed in 2021 were adopted by the laboratory. Findings are as follows: The laboratory performed Hematology and Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 11/09/22. A. Hematology 1. A Beckman Coulter DxH 690T hematology analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began using this analyzer to perform Complete Blood Count (CBC) testing in August 2021. The CBC included the following regulated analytes: WBC - White Blood Cells RBC - Red Blood Cells HGB - Hemoglobin HCT - Hematocrit PLT - Platelets 3. PV activities on the DxH 690T analyzer were completed in August 2021 as indicated in laboratory records found in the Performance Verification Data Manual, DxH690T and confirmed by the GS during the laboratory tour. 4. The WBC and RBC upper reportable range limits adopted by the laboratory 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 600/690T procedure found in Policystat, the laboratory's policy management software. See below. Analyte PV Adopted WBC 0-384.6 0-399.9 RBC 0-7.95 0-8.08 5. In an interview at 3:10 p.m. on 11/09/22, the Technical Supervisor confirmed the above finding. B. Chemistry 1. An Abbott Alinity chemistry analyzer was observed as present and available for use during the tour of the laboratory. The laboratory completed PV activities for Acetaminophen (ACE) and Salicylates (SAL) in December 2021 as indicated in laboratory records found in the Acet/Sali Validation folder. 2. The ACE and SAL upper and/or lower reportable range limits adopted by the laboratory did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated in the PV documents and the Acetaminophen on the Alinity System Plasma/Serum and Salicylate on Alinity System procedures found in Policystat. See below. Analyte PV Adopted ACE 10.3-349.33 17-378 SAL 10.10-96.80 5-100 3. The laboratory performed 63 ACE and 57 SAL tests on patient samples since the 12/27/21 implementation date as indicated by the laboratory on 11/09/22 . 4. In an interview at 1:15 p.m. on 11/09/22, the Technical Supervisor confirmed the above finding. .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit

	of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform calibration verification on a Hematology analyzer at least once every 6 months in 2022. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor during a tour of the laboratory at 8:10 a.m. on 11/09/22. 2. A Beckman Coulter DxH 690T hematology analyzer was observed as present and available for use during the tour. 3. DxH 690T calibration verification was required every six months as indicated in the Beckman Coulter DxH 600/690T procedure found in the Policystat, the laboratory's policy management software. 4. Calibration verification was performed in August 2021 during installation of the analyzer and in November 2022 as indicated in laboratory records. Documentation for a calibration verification performed in early 2022 was not found. The laboratory was unable to provide the missing documentation upon request. 5. In an interview at 3:10 p.m. on 09/07/22, the Technical Supervisor confirmed the above finding and indicated the calibration verification due in February 2022 was not performed.