Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0406035	11/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Centracare Clinic St Joseph	1360 Elm St E, Saint Joseph, 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
D0000	The CentraCare Clinic St Joseph laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F. R. part 493) upon completion of the recertification survey performed on November 20, 2023. The following standard-level deficiencies were cited: 493.801 Enrollment and testing of proficiency samples 493.1253 Establishment and verification of performance specifications .
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: . Based on laboratory document review and Centers for Medicare and Medicaid Services (CMS) report review, the laboratory failed to ensure proficiency testing results for six of six regulated Chemistry analytes tested by the laboratory were released to CMS in 2022 and 2023 as required. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 10:15 a.m. on 11/20/23. 2. An i-STAT blood analyzer was observed as present and available for use during the tour. The laboratory performed testing for the following regulated Chemistry analytes using the i-STAT CHEM8+ cartridge: Sodium Potassium Chloride Glucose Urea Nitrogen Creatinine 3. The laboratory participated in proficiency testing (PT) using the College of American Pathologists (CAP) provider. CAP PT result documents from 2022 and 2023 were reviewed on date of survey. PT performance documentation for the i-STAT CHEM8+ analytes was found for 2022 and 2023 during review 4. PT results for the six regulated Chemistry analytes from the 2022 and 2023 CAP PT

	events were not found during CMS database review completed on 11/17/23. The Individual Laboratory Profile report from the database was provided to the laboratory on 11/20/23. The report included Hematology analyte results but no Chemistry analyte results. 5. In an interview at 11:57 a.m. on 11/20/23, the LD 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 Hematology reportable ranges obtained during performance verification (PV) activities were adopted by the laboratory in 2022. Findings are as follows: 1. The laboratory performed moderate complexity Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 10:15 a.m. on 11/20/23. 2. A Beckman Coulter DxH 520 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 testing in March 2022 as indicated by the LD. 3. PV activities on the DxH 520 analyzer were completed in March 2022 as indicated in laboratory records found in the Performance Verification Data Manual. The former LD approved the PV on 03/09/22. 4. The Hematocrit (HCT) and Hemoglobin (HGB) 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 laboratory documents. See below. Analyte PV Adopted HCT 6.8-72.9 0.0-85.0 HGB 0.01-19.20 0.2-25.0 4. In an interview at 1:20 p.m. on 11/20/23, the LD confirmed the above finding. .