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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>24D0406035 | <b>(X3) Date Survey Completed</b><br>11/21/2025 |
| <b>Name of Provider or Supplier</b><br>Centracare Clinic St Joseph   | <b>Street Address, City, State</b><br>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. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D0000</b>              | 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 21, 2025. The following standard-level deficiencies were cited: 493.1413 Technical consultant responsibilities .  |
| <b>D6045</b>              | <p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b><br/>CFR(s): 493.1413(b)(7)</p> <p>(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;</p> <p>This STANDARD is not met as evidenced by:<br/>                     . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to ensure initial training and competency assessment for a new hematology analyzer was performed and documented for four of four testing personnel (TP) in 2023. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 12:05 p.m. on 11/21/25. 2. An Alcor Scientific mini iSED ESR analyzer was observed as present and available for use during the tour: The laboratory began testing patients using this analyzer in November 2023 as indicated by the TC and confirmed in laboratory records.. 3. Initial training and competency assessment of testing personnel was required before testing specimens independently as established on the New Employee Training Checklist and Competency Verification Form found in the Laboratory QA Manual Book #1. 4. Initial mini iSED ESR analyzer training and competency assessment documentation for TP1, TP2, TP3, and former TP MG was not found during review of 2023 laboratory records. The laboratory was unable to provide the missing documents upon request. 5. In an interview at 3:05 p.m. on 11/21 /25, the TC confirmed the above finding. The TC stated an on-line training module</p> |

provided by the manufacturer had been completed by the TP but no documentation was obtained. .