

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D0927853	<b>(X3) Date Survey Completed</b> 01/02/2025
<b>Name of Provider or Supplier</b> Centracare - Becker Clinic	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The Centracare Becker Clinic 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 January 2, 2025. The following standard-level deficiencies were cited: 493.1291 Test Report 493.1413 Technical consultant responsibilities .
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure one of two test reports reviewed on date of survey were accurately entered in the patient electronic medical record (EMR) in 2024. Findings are as follows: 2. The laboratory performed chemistry testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 10:34 a.m. on 01/02/25. 3. An Abbott iSTAT chemistry device was observed as present and available for use during the tour of the laboratory. The laboratory performed 9,731 chemistry tests in 2024 as indicated on the Form CMS-116 provided by the laboratory on date of survey. 4. Patient #026 received Basic Metabolic Panel (BMP) chemistry testing on 10/2/24 as indicated on the iSTAT Patient Log. 5. The Anion Gap result included in the BMP was misreported in the patient's EMR. See below: iSTAT Patient Log result: Anion</p>

Gap 14.5 mmol/L EMR Test Report result: Anion Gap 16 mmol/L 6. In an interview on 01/02/25, the LD confirmed the above finding. .

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to ensure two of two tenured testing personnel were evaluated for test procedure competency in all testing areas in 2023 and 2024. Findings are as follows: 1. The laboratory performed Bacteriology, Mycology, Parasitology, Chemistry, and Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 10:34 a.m. on 01/02/2025. 2. The following instruments, equipment, and devices were observed as present and available for use during the tour: Abbott iSTAT chemistry device Triage Meter chemistry device Beckman Coulter DXH520 hematology analyzer Alcor Mini iSED hematology analyzer Olympus CH30 microscope 3. The Personnel Assessment Procedure in the Quality Assurance Manual provided by the laboratory indicated testing personnel were evaluated for competency in all testing areas during initial training, after six months, after one year and annually thereafter. 4. Competency assessments for two of two testing personnel were not found for 2023. 5. Competency assessments for two of two testing personnel included one of six required elements for 2024. Blind sample evaluations were completed for both testing personnel. 6. The laboratory was unable to provide the missing competency assessments upon request. 7. In an interview at 11:32 a.m. on 01/02/2025, the LD confirmed the above finding. .