

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0927853	(X3) Date Survey Completed 12/06/2018
Name of Provider or Supplier Centracare - Becker Clinic	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of non-graded proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 12/06/18 at 10:00 a.m. 2. The laboratory performed PT using the College of American Pathologists (CAP) PT provider. 3. The laboratory received non-graded results from CAP due to no consensus in Chemistry and Hematology for the events and tests listed below. The Data Summaries from CAP with the expected results for these tests were not included in the laboratory's records. Event Sample ID Test 2017 SEM-A UA-03 Semen Analysis 2018 CM-B USP-04 Urine Sediment 4. An evaluation of the non-graded PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 12/06/18 at 12:10 p.m., the LD confirmed an evaluation of the non-graded PT results was not performed.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:
. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to verify the accuracy of all tests performed at least twice annually. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 12/06/18 at 10:00 a.m. 2. A Polymedco Sedimat 15 Plus automated sedrate analyzer was observed as present and available for use during the tour. The laboratory performed Erythrocyte Sedimentation Rate (ESR) testing using this analyzer. 3 The laboratory performed PT using the College of American Pathologists (CAP) as the Proficiency Testing (PT) provider. One completed CAP ESR PT event was found in 2017 laboratory records. The laboratory was unable to provide documentation of additional 2017 ESR verification of accuracy upon request. 4 In an interview on 12/06/18 at 11; 45 a.m., the LD confirmed the above findings.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of manually entered test results. Findings are as follows: 1. The laboratory manually entered test results from non-interfaced test systems into the Epic/Beaker laboratory information system. 2. The Centracare Clinic-Becker Laboratory Quality Assurance Plan located in the Quality Assurance Manual indicated the accuracy of manually entered test results was verified quarterly. 3. Documentation of the quarterly verification of manually entered test results was not found during review of laboratory records. The laboratory was unable to provide this documentation upon request. 4. In an interview on 12/06/18, at 1:10 p.m. the LD stated quarterly verification of manually entered test results was not routinely performed.

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 document review and interview with laboratory personnel, the technical consultant (TC) failed to evaluate required Hematology and Chemistry competency assessment elements for all testing personnel (TP) in 2017. Required elements include; 1) Direct observation of test performance, 2) Monitoring the recording and

reporting of test results, 3) Review of intermediate test results or worksheets and records, 4) Direct observation of instrument maintenance, 5) Assessment of test performance with previously analyzed specimens, and 6) Assessment of problem solving skills. Findings are as follows: The laboratory performed Hematology and Chemistry testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 12/06/18 at 10:00 a.m. A. Microbiology 1. The laboratory performed Vaginal Wet Preparations, KOH microscopic examinations under the Microbiology specialty. 2. The 2017 Annual Competency records for 2 of 3 tenured TP reviewed on date of survey were incomplete. See below. Vaginal Wet Preparations TP Missing elements TP1 1, 2, 3, 5, 6 TP2 1, 2, 3, 5, 6 KOH Microscopic examinations TP Missing elements TP2 1, 2, 3, 5, 6 3. In an interview on 12/06/18 at 11:10 a.m., the LD confirmed the 2017 Microbiology competency assessments were incomplete for the TP1 and TP2. B. Hematology 1. The laboratory performed Complete Blood Count (CBC) using the Beckman Coulter AcT 5diff CP hematology analyzer under the Hematology specialty. In addition, the laboratory performed Erythrocyte Sedimentation Rate (ESR) testing on the Polymedco Sedimat 15 analyzer and Post-Vasectomy microscopic examinations. 2. 2017 hematology competency assessment records for 3 of 3 tenured TP reviewed on date of survey were incomplete. See below. Beckman Coulter AcT 5diff CP TP Missing elements TP2 1, 2, 4, 6 TP3 1, 2, 4, 5, 6 Polymedco Sedimat 15 TP Missing elements TP1 1, 2, 3, 5, 6 TP2 1, 2 TP3 1, 2, 3, 5, 6 Post-Vasectomy TP Missing elements TP1 1, 2, 3, 4, 5, 6 TP2 1, 2, 3, 4, 6 TP3 1, 2, 3, 4, 5, 6 3. In an interview on 12/06/18 at 11:10 a.m., the LD confirmed the 2017 Hematology competency assessments were incomplete for TP1, TP2 and TP3. C. Chemistry 1. The laboratory performed Troponin and B-type Natriuretic Peptide testing using the Alere Triage Meter Plus and Urine Sediment microscopic examinations under the Chemistry specialty. 2. 2017 Chemistry competency assessment records for 3 of 3 tenured TP reviewed on date of survey were incomplete. See below. Alere Triage Meter Plus TP Missing elements TP1 1, 2, 4, 6 TP2 1, 2, 4, 6 TP3 1, 2, 4, 5, 6 Urine Sediment TP Missing elements TP2 1, 2, 3, 4, 5, 6 TP3 1, 2, 3, 4, 5, 6 3. In an interview on 12/06/18 at 11:10 a.m., the LD confirmed the 2017 Chemistry competency assessments were incomplete for TP1, TP2 and TP3.