

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0406035	(X3) Date Survey Completed 03/29/2018
Name of Provider or Supplier Centracare Clinic St Joseph	Street Address, City, State 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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</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 hematology proficiency testing samples were tested consistent with the number of times the laboratory routinely tested patient samples. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Technical Consultant 2 (TC2) during a tour of the laboratory on 03/29/18 at 10:00 a.m. A Beckman Coulter AcT 5diff hematology analyzer was observed as present and available for use during the tour. 2. The laboratory performed proficiency testing (PT) for Hematology using the College of American Pathologists (CAP) proficiency testing provider. 3. Hematology PT samples FH10-06 through FH10-10 from the CAP 2017 FH10-B event were tested on multiple days as indicated on test result documents generated by the Beckman Coulter AcT 5diff hematology analyzer. See below for dates and time of day testing was performed. 05/10/17 05/10/17 05/15/17 Sample FH10-06 1:39 2:25 10:51 FH10-07 2:27 2:32 10:54 FH10-08 1:49 1:55 10:56 FH10-09 1:56 2:30 10:57 FH10-10 2:00 2:02 10:59 4. In an interview on 03/29/18 at 1:45 p.m., TC2 confirmed the PT samples had been tested on multiple days and patient specimens would not routinely be handled in this manner.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p>

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the technical consultant failed to ensure competency was assessed at least semiannually during the first year of patient specimen testing for 1 of 2 new testing personnel. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry and Hematology testing as confirmed by Technical Consultant 2 (TC2) during a tour of the laboratory on 03/29/18 at 10:00 a.m. 2. Testing Personnel 1 (TP1) was listed on the Laboratory Personnel Report (CLIA) Form CMS-209 as a full time employee performing moderate complexity testing. 3. Laboratory records indicated TP1 was trained and initially assessed for testing competency in December 2015 through February 2015. 4. A semiannual competency assessments for TP1 was not found during review of laboratory records. The laboratory provided a competency assessment labeled "6 month" which was performed in December 2016; 10 months after the initial competency assessment was completed. 5. In an interview on 03/29/18 at 10:55 a.m., TC2 confirmed the semiannual competency assessment for TP1 was completed after the 6 month timeframe had been exceeded. *This is a repeat deficiency. This issue was previously cited during the 11/18/15 survey.*