Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405460	07/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Centracare - Benson	1815 Wisconsin Ave, Benson, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director or designee failed to review and evaluate proficiency testing (PT) results for 1 of 14 PT events in 2017. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 7/19/18 at 11:05 a.m. 2. The laboratory performed Proficiency Testing (PT) using American Proficiency Institute (API) as the provider. 3. Review of API PT documents revealed the following results were graded as unacceptable: Year: 2017 Survey: Chemistry / Core Event: 3rd Sample: CH-14 Tests: Lactic Acid 4. Documentation of review and corrective actions for the unacceptable result was not found. The laboratory was unable to provide the above records upon request. 5. In an interview at 11:45 a.m. on 7/19/18, the GS confirmed the above findings. .
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure accurate reference ranges, critical values ranges, and units of

	expression were listed on Chemistry, Endocrinology, Hematology and Coagulation final patient reports and/or test procedures were correct Findings are as follows: 1. The laboratory performed Chemistry, Endocrinology, Hematology and Coagulation testing as confirmed by General Supervisor (GS) during a tour of the laboratory on 7 /19/18 at 11:05 a.m.. 2. Reference range, critical values range, and units of expression discrepanies were revealed during review of final patient test reports and test procedures for the following tests: - Lactic Acid: The Critical Values & Test Protocol, located in the General Lab Policies and Procedures Manual, listed the Lactic Acid critical value range = >4.0 mmol/L. The Lactic Acid - EXL procedure, located in the Chemistry Procedures Manual, listed the Lactic Acid critical value range = >5.0 mmol /L. - bHCG*: A final patient test report reviewed on the date of the survey (Date performed = 2/15/18, Female / 29 yrs), listed the bHCG units of expression = mIU /mL. The bHCG - EXL procedure, located in the Chemistry Procedures Manual, listed the bHCG units of expression = IU/L. - Basophil Count, Absolute: A final patient test report reviewed on the date of the survey (Date performed = 1/22/17, Female / 50 yrs), listed the Basophil Count, Absolute reference range = 0.0 - 0.2 The C-0282 CBC / Differential Using the XS-1000i procedure, located in the Hematology Procedures Manual, listed the Basophil Count, Absolute reference range = 0.0 - 2.0 - D-Dimer: A final patient test report reviewed on the date of the survey (Date performed = 4/26/18, Female / 12 yrs), listed the D-Dimer units of expression = ng/L. The D-Dimer Triege Meter procedure, located in the Hematology Procedures Manual, listed the D-Dimer units of expression = ng/mL. 3. In an interview on 7/19/18 at 3:25 p.m., the GS confirmed the above findings. *bHCG = Beta-Human Chorionic Gonadotropin .