Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405460	07/11/2022
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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). 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 one 2020 non-graded proficiency testing (PT) result for a non-regulated analyte when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Urinalysis testing as confirmed by the General Supervisor during a tour of the laboratory at 8:15 a.m. on 07/07/22. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. One Urine Sediment (US) result from the third 2020 Hematology/Coagulation PT event was not graded by API due to lack of consensus. See below. Sample ID Analyte US-06 US 4. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test result. The data summary for the above sample was not present in laboratory records. An evaluation of the non-graded result was not found in laboratory records. The laboratory was unable to provide an evaluation of the non-graded result upon request. 5. The laboratory's Proficiency Testing Procedure found in the General Laboratory policy and procedure manual indicated the manager would review and evaluate all non-graded PT results. 6. In an interview at 10:45 a.m. on 07/07/22, the Technical Supervisor confirmed the above finding. .
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f)

	(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document alarm system function checks for the blood storage refrigerator in 2020 and 2021 with the frequency defined by the laboratory. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on at 8:15 a.m. on 07/07/22. 2. The laboratory stored blood products in a designated refrigerator. The blood storage refrigerator had a temperature alarm system. 3. Monthly blood product storage alarm check requirements were established on the Blood Bank Alarm Checks form. 4. Blood product storage alarm checks were not performed on one of twelve required occasions in 2020 and on one of twelve required occasions in 2021 as indicated on the Blood Bank Alarm Checks form. The alarm checks were not completed in December 2020 and August 2021. 5. The laboratory provided approximately 246 Immunohematology results to patients annually as indicated on the Form CMS-116 provided by the laboratory on date of survey, 07/07 /22. 6. In an interview at 2:45 p.m. on 07/07/22/22, the Technical Supervisor confirmed the above finding. 7. The laboratory was given five days to provide documentation of alarm checks completed by an outside vendor. In an email received on 07/11/22 at 7:08 a.m., the GS indicated no other alarm check records were found. .
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 failed to ensure five of six testing personnel in 2020 and six of six testing personnel in 2021 were evaluated for test procedure competency in all testing areas. Findings are as follows: 1. The laboratory performed Endocrinology testing as confirmed by General Supervisor during a tour of the laboratory at 8:15 a.m. on 07/07 /22. 2. Cardinal Health hCG test kits were observed as present and available for use during the tour. The laboratory used serum for this test as indicated by the GS during the tour. 3. The laboratory's Technical Competency procedure, found in the General Laboratory policy and procedure manual, indicated TP were evaluated for competency in all testing areas during training, after 6 months of work, and annually thereafter. 4. Competency assessments for Serum hCG testing were not included in the Competency Assessment forms completed for 5 of 6 testing personnel in 2020 and 6 of 6 TP in 2021. 5. The laboratory was unable to provide the missing evaluations upon request. 6. In an interview at 9:55 a.m. on 07/07/22, the Technical Supervisor confirmed the above finding.