Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405629	09/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Centracare - Redwood	101 Caring Way, Redwood Falls, 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
D0000	The CentraCare - Redwood 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 September 26, 2024. The following standard-level deficiencies were cited: 493.1271 Immunohematology 493.1445 Laboratory director responsibilities 493.1451 Technical supervisor responsibilities .
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 with the frequency defined by the laboratory in 7 of 24 months in 2022, 2023, and 2024. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by the General Supervisor during a tour of the laboratory at 8:05 a.m. on 09/26/24. 2. A blood product designated refrigerator with a temperature alarm system was observed as in use during the tour. 3. Monthly blood product storage alarm check requirements and activities were established on the Blood Bank Maintenance Log and in the Alarm Activation Procedure provided by the laboratory. 4. Alarm checks were not completed on seven occasions in the time period reviewed, September 2022 through August 2024 as indicated on the Blood Bank Maintenance Log. See below. Months alarm checks were not performed 2022

	December 2023 January February May November 2024 February August 5. The laboratory performed approximately 1057 Immunohematology results annually as indicated on the Form CMS-116 provided by the laboratory on date of survey. 6. In an interview at 4:00 p.m. on 09/26/24, the Technical Consultant confirmed the above finding. .
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director failed to ensure 7 of 7 tenured testing personnel received comprehensive competency evaluations at least annually in 2023. Findings are as follows: 1. The laboratory was cited for incomplete annual competency evaluations during the previous survey conducted on 08/19/22. 2. Annual competency evaluations from 2023 were found incomplete on date of current survey, 09/26/24, for 7 of 7 tenured testing personnel. See D6128. 3. In an interview at 12:50 p.m. on 09/26/24, the Technical Consultant confirmed the above finding. .
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Supervisor failed to complete comprehensive competency assessments at least annually for seven of seven tenured testing personnel (TP) in 2023. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, Hematology, and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 09/26/24. 2. The following non-waived test systems, analyzers, devices, and test kits were in use in 2023 as indicated by the GS during the tour: Siemens Dimension EXL chemistry analyzer Quidel Triage Meter Pro chemistry analyzer MedToxScan toxicology analyzer Cell Dyn Ruby hematology analyzer Sysmex CA-660 coagulation analyzer Adeza TLiLQ system - Fetal Fibronectin BioRad Immunohematology test system Microscopes and stains for microscopic examinations Fungal exam (KOH) Vaginal preparation (VWP) Gram Stain Manual differential Body fluid cell counts Consult hCG Combo test kit 3. Annual competency assessments were required for all testing personnel as established in the Job Competency Verification for Testing Staff procedure provided by the

	laboratory. 4. Annual competency assessment documentation for the above tests was incomplete on the 2023 competency evaluation forms for the following TP: TP1, TP2, TP3, TP4, TP8, TP9, and GS. See below. Required elements DO - Direct observation of test performance TR - Monitoring test result recording and reporting RV - Review of worksheets and records M - Direct observation of equipment maintenance B - Assessment using blind samples PS - Assessment of problem solving skills EXL TP9 - DO, TR, RV GS - DO Triage TP1 - B TP2 - B TP4 - B TP8 - TR MedToxScan GS - DO Cell Dyn Ruby TP1 - B TP2 - B TP3- B TP4 - B TP9 - B GS - M Sysmex CA-660 TP1 - B TP2 - B TP3- B GS - M Adeza Ffn TP3 - B Immunohematology TP4 - B VWP/KOH TP1 - B, PS TP2 - M, B, PS TP3 - TR, M, B, PS TP4 - TR, M, B, PS TP8 - TR, M, B, PS TP9 - TR, M, B, PS GS - TR, M, B, PS Gram Stain TP1 - M, B TP2 - TR, M, B TP3 - TR, M TP4 - TR, M, B GS - TR, B Manual differential TP1 - M, PS TP3 - M, PS TP4 - M, B GS - B Body fluid cell count TP1 - DO, TR, B, PS TP3 - TR, M, PS TP4 - M, PS GS - DO, TR, B, PS Serum hCG TP4 - B TP8 - B 5. The laboratory was unable to provide additional documentation upon request. 6. In an interview at 12:50 p.m. on 09/26/24, the Technical Consultant confirmed the above finding. *This is a repeat deficiency. The issue was cited during the 08/19/22 survey. See D6103* .