Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0662524	08/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
Midwest Transplant Network	1900 W 47th Place Suite 400, Westwood, KS	

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	A validation survey was conducted on August 27, 2025. Standard-level deficiencies were cited.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) (d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's sample acceptance and rejection criteria policy, the laboratory test requisition form, a client donor testing agreement and interview with the Laboratory Director, the laboratory failed to provide clients a defined room temperature range for transport of specimens for six of six laboratory tests. Findings include: 1. A review of the LO-CPA 2.1 Sample Acceptance and Rejection Criteria policy, v.11, Table 1, revealed the following laboratory test information: a. ABO Typing Specimen Preservation - Maintain blood at room temperature. b. Anti-A IgG Titer Specimen Preservation - Maintain blood at room temperature. Separated serum may be frozen. c. HLA Typing Specimen Preservation - Blood samples and buccal swabs - maintain at room temperature. d. Engraftment Analysis Specimen Preservation - Blood samples and buccal swabs - maintain at room temperature. e. HLA Antibody Screening, Single Antigen and C1q Testing Specimen Preservation - Refrigerated (2-8C) or room temperature. f. Flow cytometry Crossmatch Specimen Preservation - Maintain blood at room temperature 2. A review of the laboratory test requisition form, LA-REQ-LB: 6217 (R10:01/25), revealed the following: a. Test: HLA Typing Specimen Requirements: One 5 ml EDTA Tube (Lavender Top) b. Test: ABO Typing Specimen Requirements: One 10 ml Clot Tube (Red Top) c. Test: Antibody Screen/DSA/Non-HLA Specimen Requirements: One 10 ml Clot Tube (Red Top) d. Test: Flow Cytometry Specimen Requirements: Recipient, one 10 ml Clot

	Tube (Red Top). Potential Donor, one 5 ml EDTA (Lavender Top); three 10 ml Acid Citrate Dextrose Tubes (Yellow Top). e. Test: Engraftment Analysis Specimen Requirements: Peripheral Blood, one 5 or 10 ml EDTA (Lavender Top). Bone Marrow, specimen should be drawn without anticoagulant, then transferred to a 5 ml EDTA Tube (Lavender Top). 3. A review of a client donor testing agreement describing testing protocols for Heart, Kidney, Kidney-Liver, Kidney-Heart, Kidney-Pancreas, Pancreas islet and Liver, and Hematopoietic Stem Cell transplant revealed the following laboratory tests with specimen type and quantity requirements only, no temperature requirements stated: a. ABO b. A1 Titer c. HLA Typing d. Antibody Testing/Donor Specific Antibody (DSA) Testing e. Crossmatch f. Chimerism Testing 4. During an interview on 08/27/2025 at approximately 3:00 PM, the Laboratory Director confirmed there were no defined temperature requirements for specimen transport provided to clients for the six of six laboratory tests mentioned above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's sample acceptance and rejection criteria policy and interview with the Laboratory Director, the laboratory failed to define and monitor the room temperature range essential for preservation of specimen for six of six laboratory tests. Findings include: 1. A review of the LO-CPA 2.1 Sample Acceptance and Rejection Criteria policy, v.11, Table 1, revealed the following laboratory test information: a. ABO Typing Specimen Preservation - Maintain blood at room temperature. b. Anti-A IgG Titer Specimen Preservation - Maintain blood at room temperature. Separated serum may be frozen. c. HLA Typing Specimen Preservation - Blood samples and buccal swabs - maintain at room temperature. d. Engraftment Analysis Specimen Preservation - Blood samples and buccal swabs - maintain at room temperature. e. HLA Antibody Screening, Single Antigen and C1q Testing Specimen Preservation - Refrigerated (2-8C) or room temperature. f. Flow cytometry Crossmatch Specimen Preservation - Maintain blood at room temperature 2. During an interview on 08/27/2025 at approximately 3:00 PM, the Laboratory Director confirmed there was no defined room temperature range in the specimen accessioning area and no record of specimen temperatures upon receipt in the laboratory for the six of six laboratory tests mentioned above.