Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0646600	04/02/2026
Name of Provider or Supplier	**Street Address, City, State**	
Transplant Immunology Lab Nw Univ	303 E Chicago Ave Tarry Bld Ste 11-701, Chicago, IL	

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
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(g) (d)(3)(v) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on general supervisor 2 interview and next-generation sequencing (NGS) quality control record review on April 2, 2026 at 09:25 am, the laboratory failed to include two quality control materials at least once a day patient molecular amplification NGS specimens were assayed. Findings included: a. In histocompatibility, the laboratory performed patient specimen HLA typing assays using NGS protocols. b. Although the laboratory included a negative quality control material each day patient NGS HLA typing assays were performed, the laboratory maintained no documentation to indicate that a quality control material with a known HLA typing result was assayed each day patient NGS HLA typing assays were performed. c. The general supervisor 2 confirmed these findings on April 2, 2026 at 09:25 am. d. According to general supervisor 1, the laboratory performed and reported approximately 2,771 patient HLA typing results annually.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) 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 general supervisor 1 and laboratory personnel interviews and written laboratory personnel competency policy record review on April 1, 2026 at 09:45 am, the laboratory director, high complexity testing, failed to ensure that written procedures were 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 tests procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings included: a. Although the laboratory maintained documentation to indicate it had met the CLIA regulations at 42 CFR 493.1451 (b)(8) and (9), the laboratory maintained no written protocols detailing the procedures used to conduct laboratory personnel competency activities. b. These findings were confirmed by general supervisor 1 and laboratoroy personnel on April 1, 2026 at 09:45 am. c. According to laboratory documentation, the laboratory performed and reported approximately 37,193 patient tests annually.