Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0662659	03/05/2026
Name of Provider or Supplier	**Street Address, City, State**	
Donor Network Of Arizona	2010 W Rio Salado Pkwy, Tempe, AZ	

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	An onsite validation survey was conducted on 03/05/2026, and standard level deficiencies were cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on an interview with staff, and a review of the laboratory's policies and procedures, the laboratory failed to establish policies and procedures for the proper storage and transport of specimens for two of two years (2024-2025). a. An interview with the Associate Vice President of Clinical Services on 03/05/206 at 11:59 AM, in the conference room, revealed that specimens are collected from across the state and transported to the laboratory via courier for deceased donor ABO and HLA phenotyping testing. b. The laboratory was asked to provide policies and procedures for the storage and transport of specimens. No documentation was provided. c. An interview with the Laboratory Director, the General Supervisor, and the Associate Vice President of Clinical Services on 03/05/2026 at 3:45 PM, in the conference room, confirmed the findings.
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: I. Based on direct observation, manufacturers' instructions, the laboratory's documentation, and interviews with staff, the laboratory failed to define acceptable humidity ranges and to monitor and document humidity according to the manufacturers' instructions for two years (2024-2025). a. A tour of the laboratory at 10:26 AM revealed 1 Qiagen EZ1 Advanced XL in the pre-amplification room and two QuantStudios instruments in the post-amplification room. b. A review of the manufacturers' instructions revealed: "EZ1 Advanced XL User Manual", November 2017, page 90, Appendix A, "Operating conditions ...Relative humidity 15-17% (noncondensing)"; and "QuantStudio 6 and 7 Flex Real-Time PCR Systems User Guide", Revision: B, page 168, "Environmental requirements ...Humidity 15-80% (noncondensing)". c. The laboratory was asked to provide documentation it defined and monitored humidity ranges. No documentation was provided. d. An interview with the Laboratory Director, the General Supervisor, and the Associate Vice President of Clinical Services on 03/05/2026 at 3:45 PM in the conference room confirmed that the laboratory did not define acceptable humidity ranges or monitor and document laboratory humidity. II. Based on a review of the laboratory's procedure, temperature records, and interviews with staff, the laboratory failed to define an acceptable temperature range for buffy coat storage for three of three months. a. A review of the laboratory's procedure DP-IGTP406.14 "DNA Isolation-Automated Robot", page 1, "2. Specimen Collection: ...The buffy coat can be stored at 4[degrees Celsius] for up to 7 days." The procedure did not define an acceptable temperature range. b. A review of the temperature records from 12/01/2025 to 03/05/2026 for the refrigerator where buffy coat is stored revealed the temperature was approximately 10 [degrees Celsius], refer to D5785. c. An interview with the Laboratory Director, the General Supervisor, and the Associate Vice President of Clinical Services on 03/05/2026 at 3:45 PM, in the conference room, confirmed the findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by:

	Based on a review of the manufacturer's instructions, the laboratory's records, and an interview with staff, the laboratory failed to document corrective action for patient sample testing when the room temperature exceeded the manufacturer's instructions on 1 of 30 days in 09/2025. a. A review of the manufacturer's instructions for the "EZ1 Advanced XL User Manual", November 2017, pg. 90, Appendix A, revealed "Operating conditions ...Air temperature 15-30 [degrees Celsius]". b. A review of the laboratory's "Immunogenetics Laboratory Communication Sheet" for Donor ID AMIG245 32824 revealed "Start time: 1915 [Hours] ...Time 2240 [Hours]. c. A review of the laboratory's temperature log for the Pre-Amplification Room dated 09/07 /2025 revealed that room temperature exceeded 30 degrees Celsius for 27 of 42 readings between 1915 and 2240 hours. d. An interview with the Laboratory Director, the General Supervisor, and the Associate Vice President of Clinical Services on 03/05 /2026 at 3:45 PM, in the conference room, confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedure, temperature records, corrective action records, and an interview with staff, the laboratory failed to document corrective action for 54 of 54 specimens when the specimen storage temperature exceeded the acceptable limit. a. A review of the laboratory's procedure DP-IGTP406. 14 "DNA Isolation-Automated Robot", page 1, "2. Specimen Collection: ...The buffy coat can be stored at 4[degrees Celsius] for up to 7 days." The procedure did not define an acceptable temperature range; refer to D5413-II. b. A review of the temperature records from 12/01/2025 to 03/05/2026 for the refrigerator where buffy coat was stored revealed the temperature ranged between 9-12 [degrees Celsius]. c. The laboratory was asked to provide corrective action for the period when the refrigerator temperature exceeded 4 [degrees Celsius]. No documentation was provided. d. An interview with the Laboratory Director, the General Supervisor, and the Associate Vice President of Clinical Services on 03/05/2026 at 3:45 PM, in the conference room, confirmed these findings and that 54 samples were processed and stored in 12/2025.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (b)(3) Providing orientation to all testing personnel; and (b)(4) Evaluating and documenting the competency of all testing personnel. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy, competency assessment records, and an interview with staff, the laboratory failed to follow its own policy and ensure that competency assessments for three of eleven (sampling) testing personnel were performed by the delegated designee in 2025. a. A review of the laboratory's policy DP-IGTP907.11 "Quality Assurance Plan Attachment IV", page 1, "4. CLIA'88 Requirement ...A. Technologist competency assessments are done annually for all technologists in the lab. The Administrative Director or a designated technologist is

	responsible for the completion of the assessments as delegated by the Scientific Director." b. A review of the testing personnel's competency records revealed: 1. Testing Personnel (TP) #2, as listed on the CMS-209, had competency documented by TP #3. 2. TP #3, as listed on the CMS-209, had competency documented by TP #2. 3. TP #6, as listed on the CMS-209, had competency documented by TP #3. c. An interview with the General Supervisor (GS), as listed on the CMS-209, on 03/05/2026 at 10:13 AM, in the conference room, confirmed that competency assessment duties were not delegated to TP #2 and TP #3.