Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0073830	07/03/2025
Name of Provider or Supplier	**Street Address, City, State**	
The American National Red Cross, Dedham, Ma	180 Rustcraft Road Suite 115, Dedham, MA	

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 announced CLIA validation survey was conducted onsite at the American National Red Cross, Dedham, MA from June 25, 2025 to June 26,2025 by federal surveyors from the CMS DCLIQ Survey Branch, and concluded offsite on July 3rd, 2025 via email after additional documents requested were received. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to be compliance with condition-level CLIA requirements and the following standard-level deficiency were found during the CLIA validation survey
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) (a)(3)(i) Records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on review of test system performance specifications, lack of retained records and interview with laboratory staff, the laboratory failed to retain test system performance specifications records for one of six HLA test assays. Findings Included: 1. Review of test system performance specifications records on June 26, 2025 revealed, the performance specifications for the Promega PowerPlex test kit used on the Seq Studio Flex for Engraftment Monitoring was not the initial test system performance specifications. 2. The laboratory was unable to provide the initial test system performance specifications for the Promega PowerPlex test kit used on the Seq Studio Flex. 3. On June 26, 2025 at 4:00 pm, ASHI clinical consultant confirmed the test system performance specifications records were stored at an offsite facility and were not retrievable during the time of survey. Key: HLA = Human Leukocyte Antigen. ASHI = American Society for Histocompatibility and Immunogenetics.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES

	CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory competency policy, review of testing personnel (TP) competency assessment forms, and interview with laboratory staff, the laboratory failed to follow their competency assessment policy to assess and document the six elements of competency for eleven out to eleven TP. Findings Included: 1. Review of the laboratory competency policy on June 26, 2025 revealed testing personnel are assessed for the following six competency elements: a. Direct observations of assigned clinical works. b. Monitoring the accuracy of date entry and documentation. c. Review of worksheets, quality control records, proficiency testing results, and preventive maintenance records. d. Direct observations of performance of instrument maintenance and function checks. e. Assessment of performance through internal and external proficiency tests. f. Assessment of problem solving skills. 2. Review of eleven TP competency assessment records on June 26, 2025, revealed the competency assessment forms did not include the six elements of competency for each testing system TP used to performed patient testing in 2024 and 2025. 3. The laboratory staff confirmed the findings above on June 26, 2025 at 11:00 am.
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 review of laboratory policies, laboratory's online specimen collection and submission instructions, and interview with laboratory staff, one of one laboratory specimen policy failed to provide a system to ensure specimen integrity (storage and transport) was maintained. Findings Included: 1. The American Red Cross Blood Service website, HLA-typing HR Transplant Workup (11 loci) stated, "shipping information as ambient". 2. FY25 Amendment#2 BCH N0048877, sample transport, stated, "transport at ambient temperature". 3. Review of laboratory procedure on June 26, 2025 at 10:00 am revealed the laboratory did not establish an acceptable range for "ambient" temperature. 4. The laboratory specimen procedure did not include specimen temperature requirements for other specimen types. 5. In 2024, the HLA laboratory performed 44,120 HLA tests. 6. By interview on June 26, 2025 at 4:00 pm, the ASHI clinical consultant confirmed specimen transport temperatures acceptable ranges were not established or verified. Key: HLA = Human Leukocyte Antigen ASHI = American Society for Histocompatibility and Immunogenetics.
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 observation of the laboratory, lack of temperature monitoring records, and interview with laboratory staff, the laboratory failed to monitor room temperature where 16 out of 16 boxes of Sartoris Safetyspace filter Tips were stored. Finding Included: 1. Observation of the laboratory on June 25, 2025 near the freezer room revealed 16 out of 16 boxes of Sartoris Safetyspace filter Tips with a storage requirements of -20 degrees Celsius to 40 degrees Celsius. 2. The following three lots (16 boxes) were stored on a metal cart near the freezer room: a. Lot#501440099 - eight boxes. b. Lot#501317873 - two boxes. c. Lot#501334634 - six boxes. 3. The laboratory was unable to provide documented monitored temperatures where the filter tips were stored. 4. By interview, the ASHI laboratory director on June 2025 at 2:30 pm, confirmed room temperatures were not monitored or documented where the filter tips were stored. Key: ASHI = American Society for Histocompatibility and Immunogenetics
D6122	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(ii) (b)(8)(ii) Monitoring the recording and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the laboratory competency policy, review of testing personnel (TP) competency assessment forms, and interview with laboratory staff, the technical supervisor failed to establish a assessment policy to assess eleven out to eleven TP for monitoring reporting of test results. Findings Included: 1. Review of the annual Competency policy on June 26, 2025 revealed testing personnel are to be assessed for the following six competency elements: a. Direct observations of assigned clinical works. b. Monitoring the accuracy of date entry and documentation. c. Review of worksheets, quality control records, proficiency testing results, and preventive maintenance records. d. Direct observations of performance of instrument maintenance and function checks. e. Assessment of performance through internal and external proficiency tests. f. Assessment of problem solving skills. 3. Review of the laboratory competency policy and eleven TP competency assessment records on June 26, 2025, revealed the policy competency assessment forms did not include the assessment of monitoring reporting of test results. 4. The laboratory staff confirmed the findings above on June 26, 2025 at 11:00 am.