Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0194473	08/03/2023
Name of Provider or Supplier	**Street Address, City, State**	
American Natl Red Cross, Phila, Pa	700 Spring Garden Street, Philadelphia, PA	

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
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's procedures, competency assessment records, and interview with the quality director (QD), the laboratory failed to establish a competency assessment procedure to assess the competency of 3 of 4 clinical consultants (CC), 3 of 4 technical supervisors (TS), 23 of 23 technical consultants (TC) and 4 of 36 general supervisors (GS) for their supervisory responsibilities in 2021 and 2022. Findings Include: 1. On the day of the survey, 8/2/2023 at 12:28 PM, the laboratory could not provide a competency assessment procedure to assess the competency of the following personnel for their supervisory responsibilities in 2021 and 2022: - 4 of 36 GS (CMS 209 GS # 25, 29, 30 and 33) - 3 of 4 CC (CMS 209 CC # 2, 3, and 4) - 3 of 4 TS (CMS 209 TS # 2, 3 and 4) - 23 of 23 (CMS 209 TC # 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, and 23) 2. The QD confirmed the above findings on 08/03/2023 at 2:30 pm.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by:

	Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records and interview with the quality director (QD), the laboratory failed to verify the accuracy of the PT results obtained for 13 of 13 CAP immunohematology testing events reviewed for 2021 and 2022. Findings include: On the day of survey, 08 /02/2023 at 10:03 am, review of the laboratory's CAP PT records revealed that the laboratory did not verify the accuracy for the following 13 of 13 CAP immunohematology testing events for 2021 and 2022 that were not graded by the PT agency: - Transfusion Medicine-Comprehensive - J-C 2022: C, E, c, e, other antigen type, ABO subgroup. - J-B 2022: ABO subgroup, C, E, e, c, other antigen type. - J-A 2022: Antibody detection - CAP/ACMG Molecular Genetics - MGL2-A 2022 - MGL2-B 2021 - Red Blood Cell Antigen Genotyping - RAG-A 2022: Lw (a+), Lw (a-), Lw (b+, Lw (b-), V genotyping - RAG-B 2022: Lw (a+), Lw (a-), Lw (b+, Lw (b-), V genotyping - Platelet Serology - PS-A 2021: Platelet antibody - PS-A 2022: Platelet flow cytometry, platelet antibody - PS- B 2021: Platelet flow cytometry, platelet antibody - PS-B 2022: Platelet flow cytometry, platelet antibody -Transfusion Related Cell Count - TRC B 2021: leukocyte reduced RBC and platelet - TRC C 2021: leukocyte reduced RBC 2. The CAP's actions laboratories should take when a PT result is not graded document states, "the laboratory is required to review participant summary for comparative results and document performance accordingly. Evaluation criteria is not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation." 3. The QD confirmed the findings above on 08/03/2023 at 2:30 pm
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the quality director (QD), the laboratory failed to have the required records accessible and retrievable during the course of the laboratory survey performed from 08/02/2023 to 08/03/2023. Findings Include: 1. On the days of survey, 08/02/2023 and 08/03/2023, the laboratory could not provide documentation of the biannual comparisons performed in 2021, and 2022 for the following 9 of 9 tests upon request: - Platelet Crossmatch/compatibility: Platelet suspension immunoflouressence (PSIFT) vs. solid phase adherence (SPRCA) - Platelet antigen: PSIFT vs. SPRCA vs. Linkseq HPA - IgA: Flow cytometry vs.

	ELISA - Platelet antibody: PSIFT vs. SPRCA vs. bead immunoassay vs. Immucor Pak LX Assay - Antibody detection: tube vs. gel - Direct antiglobulin test: tube vs. gel - Hemoglobin S: Streck Sickledex vs. Great Lakes Diagnostic Sickleheme - Antigen typing (CcEK): Gel vs. Malditof vs. tube vs. Capture solid phase (Immucor Neo Iris) - Culture results: BacT 2. The QD confirmed the findings above on 08/03/2023 at 02:30 pm.