

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0657602	(X3) Date Survey Completed 09/16/2026
Name of Provider or Supplier Amer Nat Red Cross - Ashley, Pa	Street Address, City, State 29 New Commerce Boulevard, Ashley, 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
D0000	An on-site validation survey was completed on September 16, 2026 with the following standard level deficiency 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 a lack of procedures, review of records, and an interview with the Manager of Quality and Quality Associate #3, the laboratory failed to establish policies and procedures for immunohematology and routine chemistry patient for specimen collection, storage, and transport conditions for 2 of 2 years. 1. In the immunohematology reference laboratory (IRL), patient specimens were received and transported to the laboratory via carrier services for immunohematology and routine chemistry testing. 2. The laboratory could not provide written laboratory procedures for the collection, storage, and conditions for transport of patient specimens. 3. In an interview on September 16, 2026, at 12:00 pm, the Manager of Quality and Quality Associate #3 confirmed the above findings. 4. Review of the laboratory's test volume revealed approximately 750 immunohematology and 50 routine chemistry tests performed annually.