

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0652588	(X3) Date Survey Completed 03/26/2026
Name of Provider or Supplier American National Red Cross - Omaha, Ne	Street Address, City, State 3838 Dewey Avenue, Omaha, NE	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on technical consultant and technical supervisor interviews and preanalytic systems policies and procedures record review on March 25, 2026 at 10:30 am, the laboratory failed to established written procedures for immunohematology and routine chemistry patient specimen collection and conditions for patient specimen transportation. Findings included: a. In immunohematology and routine chemistry, it was the practice of the laboratory to receive referred patient specimens that were transported to the laboratory via carrier services. b. The laboratory maintained no written laboratory director approved procedures for the collection and conditions for transport of patient specimens. c. These findings were confirmed by a technical consultant and technical supervisor on March 25, 2026 at 10:30 am. d. According to laboratory records, the laboratory performed and reported approximately 15,002 patient immunohematology and routine chemistry tests annually.</p>
D5451	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g)</p> <p>(d)(3)(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively;</p>

This STANDARD is not met as evidenced by:

Based on technical consultant, technical supervisor, and testing personnel interviews and immunohematology unexpected antibody titer quality control record review on March 26, 2026 at 10:45 am, the laboratory failed to monitor patient immunohematology unexpected antibody titer testing using a negative quality control material and a quality control material with titered reactivity each day of patient unexpected antibody titer testing. Findings included: a. In immunohematology, it was the practice of the laboratory to perform and report test results for patient unexpected red cell antibody titer testing. b. The laboratory maintained no written documentation to indicate that a negative quality control material and a quality control material with titered reactivity was tested each day patient unexpected red cell antibody titer testing was performed and reported. c. These findings were confirmed by a technical consultant, technical supervisor, and testing personnel on March 26, 2026 at 10:45 am. d. According to laboratory personnel, the laboratory performed and reported approximately 12 patient unexpected red cell antibody titer tests annually.