

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0648317	(X3) Date Survey Completed 10/25/2022
Name of Provider or Supplier American National Red Cross Wichita, Ks	Street Address, City, State 707 North Main Street, Wichita, KS	
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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on the lack of requested procedures, and the lack of documentation for the alarm system inspection for blood and blood product storage, the laboratory failed to have a procedure for inspection of the alarm system used to monitor proper blood and blood product storage (refer to D5401) and failed to provide documentation of the inspection of the alarm system used to monitor proper blood and blood product storage temperatures (refer to D5555).</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on the tour of the laboratory, failure to provide the requested procedure and interview with General Supervisor #1 (GS #1), the laboratory failed to have a written</p>

procedure available to and followed by, laboratory personnel for the inspection of the alarm system used to monitor proper blood and blood product storage. Findings: 1. During the tour of the laboratory, the surveyors noted the presence of two refrigeration units designated for transfusion blood product storage. 2. Request was made for the procedure for inspection of the alarm system used to monitor proper blood and blood product storage. No procedure was made available at the time of survey. 3. Interview with GS #1 on 10/25/22 at 2:45 p.m. confirmed, laboratory failed to have a written procedure available to and followed by, laboratory personnel for the inspection of the alarm system used to monitor proper blood and blood product storage.

D5555

IMMUNOHEMATOLOGY
CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on the review of the document "ARC Work Order", sensor ID information on two of two refrigeration units used for the storage of blood products, and interview with GS #1, the laboratory failed to regularly inspect the alarm system for the storage of blood products for two of two refrigeration units in 2021 and to date of survey 2022. Findings: 1. Request was made for documentation of the inspection of the alarm system for two of two refrigeration units for blood product storage. The laboratory provided a document titled "ARC Work Order." This document showed testing of sensor ID 002.1520. 2. Inspection of two of two refrigeration units used for the storage of blood products revealed that neither refrigerator had a sensor ID listed as 002.1520. No other documentation of inspection of the alarm system was made available at the time of survey. 3. Interview with GS #1 on 10/25/22 at 2:40 p.m. confirmed, the laboratory failed to regularly inspect the alarm system for the storage of blood products for two of two refrigeration units in 2021 and to date of survey 2022.

D6141

GENERAL SUPERVISOR
CFR(s): 493.1459

The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.

This CONDITION is not met as evidenced by:
Based on the review of the CMS 209, temperature records review documentation, and competency assessment documents, the laboratory failed to have a qualified individual performing General supervisor responsibilities (refer to D6142), failed to ensure that oversight of the laboratory operation for temperature monitoring was

performed (refer to D6144), and failed to ensure that testing personnel competencies included assessment of test performance through previous test samples, internal blind samples or external proficiency test samples (refer to D6151).

D6142

GENERAL SUPERVISOR QUALIFICATIONS
CFR(s): 493.1461

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

This STANDARD is not met as evidenced by:

Based on the review of temperature records documentation, review of the CMS 209, and interview with GS #1, the laboratory failed to have a qualified individual performing the duties of General supervisor. Findings: 1. Request was made to review all temperature records for the laboratory. This included three room temperature and two refrigerator temperature readings. GS #1 stated those records were kept in the Distribution department. 2. Examination of the temperature records found review documentation from an individual not listed on the CMS 209. The surveyor asked this individual if he had experience in performing high complexity testing. The individual stated he did not have experience performing high complexity testing. 3. Interview with GS #1 on 10/25/22 at 1:50 p.m. confirmed, the laboratory failed to have a qualified individual performing the duties of General supervisor.

D6144

GENERAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:

Based on the review of temperature documents, and interview with GS #1, the general supervisor failed to perform oversight of temperature monitoring for all testing performed and ensuring blood and blood products were stored at the appropriate temperature. Findings: 1. Review of temperature documents for the month of October 2022 to day of survey for three room temperature thermometers and two refrigeration thermometers show no review by an individual qualified as a General supervisor. No documentation of review by qualified personnel was provided for temperature records for 2021 and to date of survey for 2022. 2. The surveyor asked GS #1 if any of the four current GS personnel reviewed the temperature documents. GS #1 stated that none of the four GS personnel reviewed temperature documents. This duty was performed by the Distribution personnel. 3. Interview with GS #1 on 10/25/22 at 1:50 p.m. confirmed, the general supervisor failed to perform oversight of temperature monitoring for all testing performed and ensuring blood and blood products were stored at the appropriate temperature.

D6151

GENERAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1463(b)(3)(4)

(3) The director or technical supervisor may delegate to the general supervisor the responsibility for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel.

This STANDARD is not met as evidenced by:

Based on the review of the delegation of duties, competency assessment documents, and interview with GS #1, the general supervisor failed to include assessment of test performance through previous test sample, internal blind sample or external proficiency testing samples in the annual competency assessment for four of four high complexity testing personnel (TP) for the year 2021 and to date of survey 2022. 1. Review of the delegation of duties document signed by the laboratory director revealed the GS was delegated the responsibility to perform annual competency assessment of all TP. 2. Request was made to review competency assessment documents for TP #3. Review of this document showed no assessment of test performance through previous test sample, internal blind sample or external proficiency testing samples. 3. The surveyor asked if this form was used to assess all testing personnel. GS #1 stated this form was used for all annual competency assessments. 4. Interview with GS #1 on 10/25/22 at 2:00 p.m. confirmed, the general supervisor failed to include assessment of test performance through previous test sample, internal blind sample or external proficiency testing samples in the annual competency assessment for four of four high complexity TP for the year 2021 and to date of survey 2022.