

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0663226	(X3) Date Survey Completed 12/04/2023
Name of Provider or Supplier American National Red Cross, The	Street Address, City, State 3747 Euclid Avenue, Cleveland, OH	
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
D6108	<p>LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447</p> <p>The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interviews with the Director, Quality Assurance Quality & Regulatory Affairs (DQAQRA) and Quality Assurance Associate Quality & Regulatory Affairs (QAAQRA), the Technical Supervisor (TS) failed to provide technical supervision to evaluate the competency of Testing Personnel (TP) #8 to assure they maintained their competency to perform moderate and high complexity test procedures and report accurate test results in the Specialty of Immunohematology. All patient testing performed by TP#8 had the potential to be affected by this deficient practice. Findings Include: 1. The TS failed to evaluate the competency of TP#8 to assure they maintained their competency to perform moderate and high complexity test procedures and report test results promptly, accurately, and proficiently in 2023. (Refer to D6120)</p>
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p>

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Director, Quality Assurance Quality & Regulatory Affairs (DQAQRA) and Quality Assurance Associate Quality & Regulatory Affairs (QAAQRA), the Technical Supervisor (TS) failed to evaluate the competency of Testing Personnel (TP) #8 to assure they maintained their competency to perform moderate and high complexity test procedures and report test results promptly, accurately, and proficiently in the Specialty of Immunohematology in 2023. All patient testing performed by TP#8 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Form CMS-209 revealed two out of 13 individuals listed as a TS. The TS individuals were qualified and credentialed by the Laboratory Director, via signature and date on 11/30/2023, to perform the functions and responsibilities as a TS. 2. Review of the laboratory's "Assessing Competency" policy and procedure, approved by the Laboratory Director and implemented on 05/06/2021 did not find instructions on who is responsible to conduct competency assessments of TP. 3. Review of the laboratory's 2023 competency assessment documentation, provided on the date of the inspection, revealed the assessment of TP#8's competency was not conducted by an individual listed and/or delegated as a TS for high complexity testing procedures. 4. Further review of the laboratory's competency assessment documentation for TP#8 and interviews with the DQAQRA and QAAQRA revealed sections of the high complexity Immunohematology assessment were conducted by an individual who was at a remote location while TP#8 was at the laboratory location as indicated for this CLIA certificate. 5. The DQAQRA and QAAQRA confirmed the laboratory's 2023 competency assessment for TP#8, conducted on 11/09/2023, was not conducted, in person, by a qualified individual who was listed and/or delegated TS or GS on the CMS-209. The interviews occurred on 12/04/2023 at 2:16 PM.