

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0651229	<b>(X3) Date Survey Completed</b>  05/02/2023
<b>Name of Provider or Supplier</b>  American National Red Cross, The	<b>Street Address, City, State</b>  100 South Robert St, Saint Paul, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6063</b>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: . Based on observation, review of personnel and laboratory documents, and interview with laboratory personnel, the laboratory failed to ensure staff performing moderate complexity testing meet the qualification requirements of 493.1423 to perform the functions specified in 493.1425 for the complexity of testing performed. Findings are as follows: The laboratory failed to obtain an equivalency evaluation of foreign credentials for one testing personnel performing moderate complexity Microbiology testing in 2023. See D6065. .</p>
<b>D6065</b>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and</p>

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to obtain a foreign credential equivalency evaluation for one of one testing personnel with foreign credentials who were performing moderate complexity Microbiology testing between 03/31/23 and 04/12/23. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the Director of Quality (DOQ) during a tour of the laboratory at 8:05 a.m. on 05/01/23. Two BacT/ALERT Microbial Detection Systems were observed in use during the tour. 2. Testing Personnel 4 (TP4) was listed on the Laboratory Personnel Report (CLIA) Form CMS-209 as an employee performing moderate complexity testing. 3. TP4 completed high school education at Victorino Mapa High School in Manila, Philippines as indicated in education credentials provided by the laboratory. 4. The Overview of CLIA Policy provided by the laboratory indicated the laboratory complied with all CLIA requirements for testing personnel. 5. An equivalency evaluation of TP4's foreign credentials was not found in personnel records. The laboratory was unable to provide the equivalency evaluation upon request. 6. TP4 completed BacT/ALERT training on 03/27/23 as indicated in a report generated on 05/01/23 from EDGE, the laboratory's education and training learning management system. 7. In an interview at 11:25 a.m. on 05/01/23, the DOQ confirmed an equivalency evaluation of foreign credentials had not been completed for TP4. 8. In an interview at 3:55 p.m. on 05/01/23, the DOQ indicated TP4 had completed BacT /ALERT testing on four donor identification numbers (DINs) separated into 10 products. 9. In an email received at 9:39 a.m. on 05/02/23, the DOQ provided an amended BacT/ALERT testing volume for TP4 as 6 DINs and 12 products. See below. Date DINs Products 03/31/2023 2 2 04/01/2023 2 4 04/12/2023 2 6