

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  47D0863491	<b>(X3) Date Survey Completed</b>  08/08/2018
<b>Name of Provider or Supplier</b>  American National Red Cross, Burlington Vt, The	<b>Street Address, City, State</b>  32 North Prospect St, Burlington, VT	
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>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview on 8/8/2018, the laboratory failed to enroll in an approved proficiency testing (PT) program in 2016, 2017 and 2018 for Immunochemistry analytes performed by the laboratory and listed in Subpart I. Findings include: 1) Review of the laboratory's test list on 8/8/2018 revealed the laboratory performed the following regulated analytes: ABO group, Rh type, antibody detection, antibody identification, and compatibility testing. 2) Review on 8/8/2018 of PT records from August 2016 to present revealed the laboratory was not enrolled in an approved PT program for the regulated analytes performed under the laboratory's active CLIA identification number. Further review revealed the laboratory performed testing and reported results for PT samples from five College of American Pathologist (CAP) PT events in 2016, nine CAP PT events in 2017, and 3 CAP PT events in 2018; all events were enrolled under a different CLIA identification number (47D0671301) belonging to a laboratory that is closed. Regulated and non-regulated analytes, events, and number of samples included in this finding are as follows: ABO Group / J B 2016, J C 2016, J A 2017, J B 2017, J C 2017, J A 2018 / five PT samples per event; Rh Type / J B 2016, J C 2016, J A 2017, J B 2017, J C 2017, J A 2018 / five PT samples per event; Antibody Detection / J B 2016, J C 2016, J A 2017, J B</p>

2017, J C 2017, J A 2018 / five PT samples per event; Antibody Identification / J B 2016, J C 2016, J A 2017, J B 2017, J C 2017, J A 2018 / five PT samples per event; Crossmatch Serology / J B 2016, J C 2016, J A 2017, J B 2017, J C 2017, J A 2018 / five PT samples per event. 3) Interview on 8/8/2018 at 10:15 a.m. with the general supervisor (GS) confirmed the laboratory was not enrolled in an approved PT program for the regulated analytes listed above. The GS revealed the laboratory was performing testing and reporting results for proficiency samples under a separate laboratory's CLIA identification number (47D0671301) and not the laboratory's own CLIA identification number. 4) Record review conducted on 08/08/2018 in the ASPEN Web Data system of CLIA ID 47D0671301 that the laboratory used for PT enrollment revealed that CLIA ID is inactive and was terminated in 1994 due to a voluntary-closure. The record review further revealed that the laboratory name was American Red Cross SCV, was a certificate of waiver (COW), and has remained inactive since 1994.