American Red Cross Biomedical Services
Washington, DC 20006

Fact Sheet: Red Cross Testing Methodologies

Screening and Confirmatory or Supplemental Test Methods

The following table lists the screening test of record and manufacturer or method. The second column lists the confirmatory, supplemental, or discriminatory testing that is routinely performed when a screening test or nucleic acid test (NAT) is reactive.

Screening Test of Record	**Additional Tests – Confirmatory, Supplemental, Discriminatory**
Manufacturer or method	**Manufacturer or method and notes**
***Trypanosoma cruzi* (Chagas)**	
Anti *T. cruzi* (Chagas): Chemiluminescent immunoassay (ChLIA) (Abbott) on PRISM	• Enzyme immunoassay (EIA) (Ortho) • Abbott Chagas Enzyme Strip Assay (Abbott ESA)
Hepatitis	
Hepatitis B surface Antigen (HBsAg): ChLIA (Abbott) on PRISM	HBsAg Confirmatory—Abbott Neutralization (PRISM) *Confirmatory is not performed when discriminatory hepatitis B virus NAT (dHBV) is reactive.*
Anti-Hepatitis B Core (Total) (HBc antibody [Ab] or anti-HBc): ChLIA (Abbott) on PRISM	TaqScreen MPX (Multiplex) Test (HBV NAT by PCR) *MPX Test is not performed when* • *HBsAg is reactive or dHBV is reactive* • *HIVAb is reactive or dHIV is reactive* • *HCVAb is reactive or dHCV is reactive*
Anti-Hepatitis C Virus (anti-HCV): ChLIA (Abbott) on PRISM	Discriminatory HCV NAT (dHCV) *No further testing is performed when dHCV is reactive.* If dHCV is negative or not tested, then the anti-HCV Supplemental (Ortho EIA) antibody test is performed.

Screening Test of Record	Additional Tests – Confirmatory, Supplemental, Discriminatory
Manufacturer or method	**Manufacturer or method and notes**
HIV	

Anti-Human Immunodeficiency Virus-1/HIV-2 (anti-HIV-1/HIV-2): ChLIA (Abbott) on PRISM
• Includes HIV-1, HIV-2, and subgroups of HIV type 1, including groups M and O
	HIV-1 Confirmatory—Sanochemia HIV-1 Immuno Fluorescence assay (IFA)
	• If HIV-1 IFA is not positive, then anti-HIV-2 EIA is performed.
	• If anti-HIV-2 is reactive, then HIV-1/2 Supplemental is performed (Bio-Rad HIV-1/2 Geenius Assay, a licensed diagnostic test for HIV-1 and HIV-2 diagnosis and discrimination).
	• The following are two exceptions when HIV-1/2 Geenius Assay is performed and HIV-2 EIA is not reactive:
	  • If the sample is IFA positive, but NAT Multiplex non-reactive (HIV-1 discordant), then HIV-1/2 Geenius Assay is performed to try to understand this discordance.
	  • If IFA is negative or indeterminate, but NAT Multiplex is reactive (HIV discordant), then HIV-1/2 Geenius Assay is performed to try to understand this discordance.

HTLV	
Anti-Human T-Cell Lymphotropic Virus I/II (anti-HTLV-I/HTLV-II): ChLIA (Abbott) on PRISM	Second licensed EIA (Ortho/Avioq) and western blot (MP Biomedicals, Ltd)
In-Process Testing	
NAT for B19 Parvovirus (Parvo NAT)	N/A — In-process test result performed by outside vendor only on donations with fractionated plasma *Only positive results are reported for market withdrawal; no donor notification.*
NAT for Hepatitis A Virus (HAV NAT)	N/A — In-process test result performed by outside vendor only on donations with fractionated plasma *Only positive results are reported for market withdrawal; no donor notification.*
Multiplex NAT	
NAT Multiplex Pool (HIV-1, HBV, and HCV) - TMA • Procleix Ultrio Plus Assay (HBV DNA, HCV RNA, and HIV-1 RNA)	Individual Multiplex NAT (ID NAT) Procleix Ultrio Plus Assay If ID NAT is reactive, then all of the following apply: • Discriminatory HIV-1 NAT (dHIV) • Discriminatory HCV NAT (dHCV) • Discriminatory HBV NAT (dHBV)
Syphilis	
Syphilis (Serologic Test for Syphilis – STS) • Olympus TP-PA (*Treponema pallidum* – partial agglutination)	Syphilis Captia G-EIA Confirmatory If EIA is reactive or indeterminate, then the Qualitative Rapid Plasma Reagin Test (RPR) is performed.

Screening Test of Record	**Additional Tests – Confirmatory, Supplemental, Discriminatory**
Manufacturer or method	**Manufacturer or method and notes**
WNV	
West Nile Virus RNA Nucleic Acid Testing: TMA • WNV NAT by TMA (Novartis) on Tigres	One or both of the following: • Supplemental WNV NAT by PCR on index sample • Repeat WNV by TMA Antibody testing (IgM/IgG) may be performed in some cases.
ZIKV	
ZIKA Virus RNA Nucleic Acid Testing: TMA NAT testing under an investigational new drug (IND) protocol	Additional testing may be performed under IND protocol.
HLA Antibodies	
HLA Class I and Class II Antibodies Qualitative Assay: ELISA Test performed on all female apheresis donations	N/A
Ferritin	
Ferritin quantitative test: Beckman Coulter (Latex agglutination – Spectrophotometer)	N/A

The American Red Cross is currently investigating selective screening options for the intraerythrocytic parasite, Babesia (common in the northeastern and mid-western sections of the U.S.). Investigational testing for Babesia is to be performed by an investigational Grifols' nucleic acid test (NAT) on donations collected in selected regions where Babesia is endemic. The Grifols' test detects 4 species of Babesia.

Additional confirmation for research testing may be done by IFA (anti-*Babesia microti*) and PCR (alternate Babesia NAT assays).

False Positive Results

The rate of false positivity exceeds that of true positivity for low-risk blood donors for the following two reasons:

- Volunteer blood donors are a uniquely healthy population who self-report an absence of symptoms or risk for blood-borne pathogens – people for whom infectious disease testing would be clinically contra-indicated.
- In order to ensure the safest possible blood supply, the Food and Drug Administration requires the use of the most sensitive tests.

This should be considered when counseling patients who may have received blood from a donor whose subsequent donation is now demonstrating a reactive screening result, but confirmatory results are not yet available.