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): Enzyme-linked immunosorbent assay (ELISA) - Ortho	Abbott Chagas Enzyme Strip Assay (Abbott ESA)
Hepatitis	
Hepatitis B surface Antigen (HBsAg): Bio-Rad GS HBsAg Enzyme Immunoassay (EIA) *Testing will start transitioning to Abbott Alinity s HBsAg chemiluminescent microparticle immunoassay (CMIA) to be completed by 11/2024.	Discriminatory HBV (dHBV) – Procleix Ultrio Elite • If reactive, then no further testing is performed. HBsAg Confirmatory-GS HBsAg Neutralization is performed **only** if either • NAT Multiplex is nonreactive or Not Tested (NT) **OR** • NAT Multiplex is reactive, and dHBV is negative or not tested. • If HBsAg Confirmatory is performed and is positive and NAT Multiplex is nonreactive or NT, then dHBV is performed (reflex).
	* HBsAg Confirmatory – Abbott Alinity HBsAg Neutralization.
Anti-Hepatitis B Core Abbott Alinity s Anti-HBc CMIA	Discriminatory HBV (dHBV) – Procleix Ultrio Elite
Anti-Hepatitis C Virus (anti-HCV): Ortho ELISA *Testing will start transitioning to Abbott Alinity s anti-HCV CMIA to be completed by 11/2024.	Discriminatory HCV (dHCV) - Procleix Ultrio Elite • If reactive, then no further testing is performed. Anti-HCV Supplemental (Abbott Alinity) antibody test is performed **only** if dHCV is negative or not tested. *Ortho anti-HCV supplemental antibody test is performed if screening test is Abbott.

Screening Test of Record	Additional Tests – Confirmatory, Supplemental, Discriminatory
Manufacturer or method	**Manufacturer or method and notes**
Human Immunodeficiency Virus (HIV)	
Anti-Human Immunodeficiency Virus-1/ HIV-2 (anti-HIV-1/HIV-2): BioRad GS HIV-1/HIV-2 Plus O EIA • Includes HIV-1, HIV-2, and subgroups of HIV type 1, including groups M and O	Discriminatory HIV NAT (dHIV) – Procleix Ultrio Elite • If reactive, then no further testing is performed. Geenius HIV-1/2 assay (HIV-1/2 confirmatory) is performed if NAT multiplex or dHIV is nonreactive or not tested. • If Geenius HIV-1/2 assay reactive, then dHIV is performed (reflex).
*Testing will start transitioning to Abbott Alinity s HIV Ag/Ab Combo assay (CMIA): Qualitative detection of HIV p24 antigen and antibodies to HIV-1 (Groups M and O), and/or HIV-2. Transition to be completed by 11/2024.	
Human T-Cell Lymphotropic Virus (**HTLV)**	
Anti-Human T-Cell Lymphotropic Virus I/II (anti-HTLV-I/HTLV-II): • Avioq HTLV -I/II ELISA *Testing will transition to Abbott Alinity s anti HTLV I/II CMIA to be completed by 11/2024.	Western blot (MP Diagnostics)
In-Process Testing	
NAT for B19 Parvovirus (Parvo NAT) – Roche PCR	N/A — In-process test result performed by outside vendor only on donations with fractionated plasma
NAT for Hepatitis A Virus (HAV NAT) – Roche PCR	N/A — In-process test result performed by outside vendor only on donations with fractionated plasma *Only positive results are entered and reported for market withdrawal, no donor notification.*

Screening Test of Record	Additional Tests – Confirmatory, Supplemental, Discriminatory
Manufacturer or method	**Manufacturer or method and notes**
Multiplex NAT	
NAT Multiplex Pool (HIV, HBV, and HCV) – TMA - Grifols • Procleix Ultrio Elite Assay (HBV DNA, HCV RNA, and HIV-1 RNA)	Individual Multiplex NAT (ID NAT) - Procleix Ultrio Elite Assay If ID NAT is reactive, then all of the following apply: • Discriminatory HIV NAT (dHIV) • Discriminatory HCV NAT (dHCV) • Discriminatory HBV NAT (dHBV)
	Low Yield Testing: Roche MPX is performed for the following: • dHIV is reactive and anti-HIV-1/HIV-2 is nonreactive • dHCV is reactive and anti-HCV is nonreactive • dHBV is reactive and HBsAg is nonreactive
Syphilis	
Syphilis (Serologic Test for Syphilis – STS) • Beckman Coulter PK-TP system (*Treponema pallidum* – partial agglutination)	Syphilis Captia G-EIA Confirmatory - Trinity If EIA is reactive or equivocal, then the Becton Dickinson - Qualitative Rapid Plasma Reagin Test (RPR) is performed.
WNV	
West Nile Virus (WNV) RNA nucleic acid testing (NAT): transcription-mediated amplification (TMA) • WNV NAT by TMA (Grifols) on Panther	Repeat WNV by TMA • If reactive, then no further testing is performed. • If nonreactive or not tested, then antibody (IgG/IgM) testing is performed.
HLA Antibodies	
HLA Class I and Class II Antibodies Qualitative Assay: ELISA Test is performed on ever-pregnant, first-time female apheresis donors, and additionally with any change in number of pregnancies	N/A
Ferritin	
Ferritin quantitative test: Beckman Coulter (Latex agglutination – Spectrophotometer)	N/A

Screening Test of Record	Additional Tests – Confirmatory, Supplemental, Discriminatory
Manufacturer or method	**Manufacturer or method and notes**
Babesia	
Licensed Babesia RNA Nucleic Acid Testing: TMA (Grifols) on Panther	• Retest Babesia RNA Nucleic Acid Testing • Babesia antibody – Immunofluorescence Assay (IFA)

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 contraindicated.
- In order to ensure the safest possible blood supply, the FDA 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.