

# Blood Donor Screening

Immuno and molecular reagents for developing blood bank screening assays



Blood transfusion is a life-saving intervention that has an essential role in patient management within health care systems. The establishment of systems to ensure that all donated blood is screened for transfusion-transmissible infections is a core component of every national blood program.

Universal screening for HIV-1, HIV-2, Hepatitis B (HBV), Hepatitis C (HCV) and Syphilis are recommended as mandatory by the World Health Organization (WHO) for the provision of a safe blood supply. These infections can cause chronic disease with possible serious consequences and present the greatest infection risk to recipients of transfusion. Infections such as malaria, Chagas disease and the human T-cell lymphotropic viruses I/II (HTLV), Zika, West Nile and CMV can also pose a significant threat to the blood supply in some countries, especially where these diseases are endemic or there is high prevalence in the general population.

## Recommended universal screening markers & assays\*:

### HIV-1 & HIV-2:



NAT or EIA/CLIA assay for HIV-1, 2 and Type O antibodies, can be used in combination with HIV-1 p24 antigen detection.

### Hepatitis B:



NAT or EIA/CLIA assay for hepatitis B surface antigen (HBsAg). Anti-hepatitis B core (HBcAg) assays can also be used as an additional marker in some countries with low HBV prevalence.

### Hepatitis C:



EIA or CLIA assay for HCV antibodies (typically against the antigens NS3, NS4 NS5 and HCV core).

### Syphilis: (*Treponema pallidum*)



EIA assay for specific treponemal antibodies (typically p15, p17, p42.5, p47 or TmpA).

\*Screening Donated Blood for Transfusion-Transmissible Infections: Recommendations. World Health Organization (WHO) Recommendations 2010.



# Universal Screening

## HIV-1 & HIV-2

**WHO Recommended:** EIA or CLIA assay for HIV-1, 2 and Type O antibodies, can be used in combination of with HIV-1 p24 antigen detection.

### Recombinant Antigens

**R01593** HIV-1 C-Terminal gp120 + most of gp41, *E. coli*

Reacts with all sera of HIV-1 and HIV-type O infected individuals and with 60-80% of HIV-2 infected individuals

**R01454** HIV-1 gp41 Type O, *E. coli*

Reacts with human HIV type O positive serum

**VTI360** HIV-2 gp36, *P. pastoris*

Contains a.a. 2212-2313 of the NS5 protein

### Antibodies

**C01653M** MAb to HIV-1 p24, pair

**C01655M** MAb to HIV-1 p24, pair

**C65690M** MAb to HIV-1 p24, pair

## Treponema pallidum (Syphilis)

**WHO Recommended:** EIA assay for specific treponemal antibodies (typically p15, p17, p42.5, p47 or TmpA).

### Recombinant Antigens

**R01681** *T. pallidum* p15/p17/p47, *E. coli*

Works in double antigen sandwich immunoassays with R01682 as the detection antigen

**R01682** *T. pallidum* p15/p17/p47, *E. coli*

Works in double antigen sandwich immunoassays with R01681 as the capture antigen

**R01705** *T. pallidum* p17/p15/p42.5/p47, *E. coli*

Chimeric protein that contains fragments of p17, p15, p42.5 and p47

**R01582** *T. pallidum* p15, *E. coli*

Contains a GST- and His-tag at the N-terminus

**R01583** *T. pallidum* p17, *E. coli*

Contains a GST- and His-tag at the N-terminus

**R8A201** *T. pallidum* p17, *E. coli*

Contains Beta-galactosidase fused at the N-terminus

**R01606** *T. pallidum* p47, *E. coli*

Contains a GST- and His-tag at the N-terminus

**R8A403** *T. pallidum* p47, *E. coli*

Contains Beta-galactosidase fused at the N-terminus

**R01665** *T. pallidum* TmpA, *E. coli*

Represents mature TmpA without the leader peptide. Contains a GST- and His-tag at the N-terminus

**R8A404** *T. pallidum* TmpA, *E. coli*

Contains Beta-galactosidase fused at the N-terminus

## HBV

**WHO Recommended:** EIA or CLIA assay for Hepatitis B surface antigen (HBsAg). Anti-Hepatitis B core antigen (HBcAg) assays can also be used as an additional marker in some countries with low HBV prevalence.

### Recombinant Antigens

**VTI610** Hepatitis B Core Virus (HBcAg), *P. pastoris*

Entire sequence of core protein (a.a.183)

### Antibodies

**C18286M** MAb to HBsAg (ad/ay), pair

**C18212M** MAb to HBsAg (ad/ay), pair

**C01247M** MAb to HBsAg (ad/ay), pair

**C01248M** MAb to HBsAg (ad/ay), pair

**B65811R** Rabbit anti-HBsAg (ad/ay), pair

## HCV

**WHO Recommended:** EIA or CLIA assay for HCV antibodies (typically against the antigens NS3, NS4 NS5 and HCV core).

### Recombinant Antigens

**VTI710** HCV Core, *P. pastoris*

**R01518** *HCV NS-3 c33c Genotype 1a, E. coli*

Contains the main immunodominant region of HCV c33c /NS3 (a.a. 1192-1459)

**R8A116** HCV NS-4a+b, *E. coli*

Contains a.a. 1658-1863 of the NS4 protein

**R18190** HCV NS-5 Genotype 1, *E. coli*

Contains a.a. 2212-2313 of the NS5 protein

**R18523** HCV Nucleocapsid NS3/NS4/NS5, *E. coli*

Contains immunodominant regions of the core, NS3, NS4 and NS5 proteins

**R01599** HCV Core NS3/NS4/NS5, *E. coli*

Contains core fragment (a.a. 11-45), NS3 fragment (a.a. 1208-1430), NS4 fragment (a.a. 1885-1923), NS5 fragment (a.a. 2332-2423). Works as a capture antigen in a pair with R01600

**R01600** HCV Core NS3/NS4/NS5, *E. coli*

Contains core fragment (a.a. 11-53), NS3 fragment (a.a. 1210-1450, 1337-1483), NS4 fragment (a.a. 1888-1925), NS5 fragment (a.a. 2332-2423). Works as a detection antigen in a pair with R01599

# Additional Screening Recommended

## Malaria (*Plasmodium* Species)

**WHO Recommended:** High sensitivity enzyme immunoassay for malaria antigens or antibodies.

### Recombinant Antigens

**R01602** *P. vivax* merozoite surface protein 1 (MSP1), *E. coli*

Suitable as a capture antigen in ELISA

**R01604** *P. vivax* merozoite surface protein 1 (MSP1), *E. coli*

Suitable as a capture antigen in ELISA

**R01440** *P. vivax* circumsporozoite protein (CSP), *E. coli*

Represents 353 amino acids of the full length protein

**R01597** *P. falciparum* lactate dehydrogenase (pLDH), *E. coli*

**R01598** *P. vivax* lactate dehydrogenase (pLDH), *E. coli*

## West Nile Virus

**CDC Recommended:** NAT assay followed by confirmatory testing for WNV-specific IgM antibodies.

### Recombinant Antigens

**R8A104** West Nile Virus Envelope Protein, *E. coli*

Contains N-terminal part of the envelope protein

## Chagas (*Trypanosoma cruzi*)

**WHO Recommended:** High sensitivity enzyme immunoassay for Chagas antibodies.

### Recombinant Antigens

**R01587** *T. cruzi* 1F8, *E. coli*

Contains a GST tag at the N-terminus

**R01589** *T. cruzi* FRA, *E. coli*

Contains a GST tag at the N-terminus

**R01684** *T. cruzi* Chimeric 1, *E. coli*

Polyprotein containing several unique immunodominant antigens. Can be used in combination with R01685 for sensitive and specific detection of Chagas

**R01685** *T. cruzi* Chimeric 2, *E. coli*

Polyprotein containing several unique immunodominant antigens. Can be used in combination with R01684 for sensitive and specific detection of Chagas

**R01364** *T. cruzi* Chimeric Multiantigen (MACH)

Polypeptide of 87 amino acids with epitopes PEP-2, TcD, TcE and SAPA

## HTLV

**WHO Recommended:** High sensitivity enzyme immunoassay for HTLV-I/II antibodies.

### Recombinant Antigens

**R18142** HTLV-I Envelope Protein

Represents C-terminal of gp46 and most of p21E (a.a. 165-440). Immunoreactive with both HTLV-I and HTLV-II positive sera.

## Zika

**FDA Recommended:** NAT assay followed by confirmatory testing for IgM antibody response.

### Recombinant Antigens

**9050** Zero-X-React™ Zika Envelope Protein, Insect Cells

Mutated to eliminate cross reactivity with other flaviviruses. Reacts with both IgG and IgM

**R01635** Zika Virus Envelope Protein, Insect Cells

Includes the ectodomain of the envelope protein. Reacts with both IgG or IgM

**R01636** Zika Virus NS1 Protein, Insect Cells

Reacts with both IgG or IgM

## CMV

**WHO Recommended:** High sensitivity enzyme immunoassay for CMV-specific IgM antibodies.

### Native Antigens

**7600** CMV IgG/IgM

Partially purified by centrifugation (strain AD169) and propagated in human MRC-5 cells

**7504** CMV-G

Cell lysate of CMV (strain AD169) and propagated in human fibroblast cells

**7507** CMV Grade III

Partially purified CMV (strain AD169) and propagated in human fibroblast cells

### Recombinant Antigens

**R01561** CMV pp52 (UL44), *E. coli*

Truncated antigen fused to His-tag at N-terminus. Suitable for IgG and IgM detection

**R01563** CMV pp150 (UL32), *E. coli*

Truncated antigen fused to His-tag at N-terminus. Suitable for IgG and IgM detection

## Pairs

	CAPTURE		DETECTION
HIV-1 p24	C65690M	Ⓡ	C01653M
	C01655M	Ⓡ	C01653M
	C01655M	Ⓡ	C65690M
HBV (HBsAg)	C01247M		B65811R
	C01248M		B65811R
	C18286M		C18212M

Ⓡ - Reversible

# Molecular Reagents

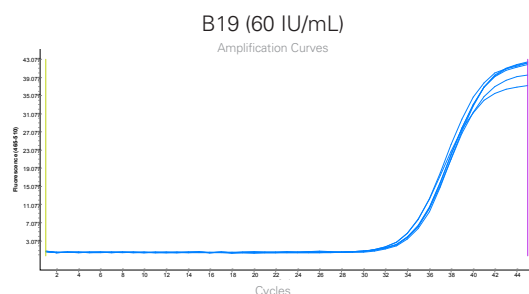
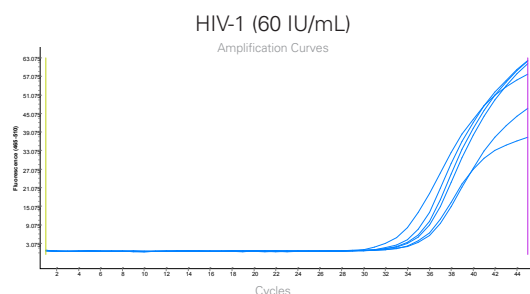
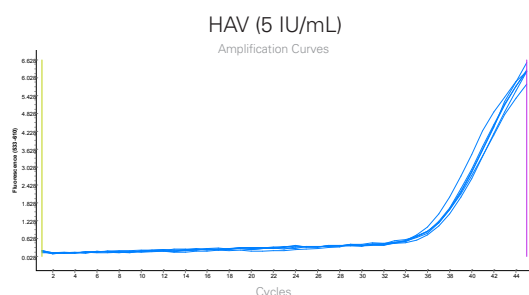
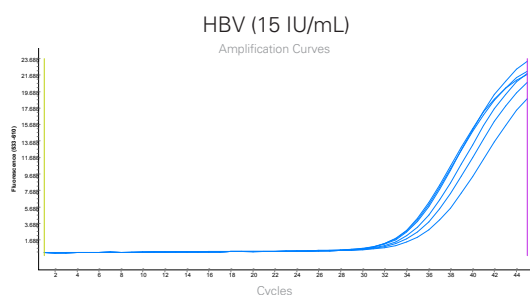
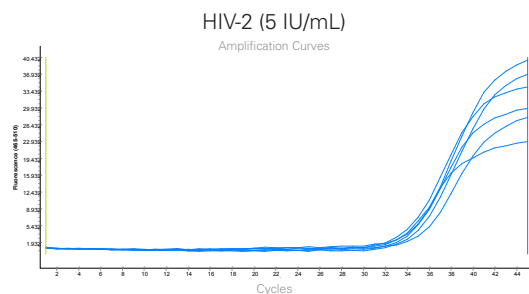
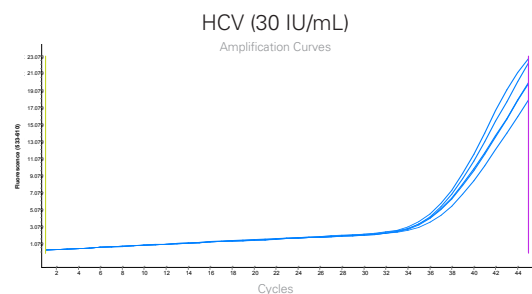
## Optimized RT-qPCR Master Mix

### MDX025 Low LOD 1-Step RT-qPCR Mix

Suitable for detecting RNA and DNA viruses at very low levels for applications such as blood bank or transplant viral testing. Novel buffer system optimized for multiplex assays. Perform first-stand DNA synthesis and qPCR in a single tube.

#### Product Performance Data:

Low Limit of Detection (LOD) for both RNA and DNA Viruses



**Method:** 24 replicates of purified blood viral extracts were tested in singleplex qPCR reactions using the Low LOD 1-Step RT-qPCR Mix at the indicated IU/mL. The singleplex reactions were HAV, HBV, HCV, HIV-1, HIV-2, Parvovirus B19. The amplification curve results illustrate that Low LOD 1-Step RT-qPCR Mix can be used with both RNA and DNA viruses as low as 5 IU/mL.

#### Sequencing Grade dNTPs

Ready-to-use sequencing grade dNTPs available individually, as sets, or pre-blended dNTP mixes. Ultra-pure (>99% by HPLC) dNTPs supplied as lithium salts. Free of PCR inhibitors, DNase and RNase. For more information visit [www.MeridianLifeScience.com](http://www.MeridianLifeScience.com).

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