

# Procleix® ULTRIO® Assay

By Gen-Probe and Novartis Diagnostics



## One tube. One test.

A single tube nucleic acid amplification test for the detection of HIV-1, HCV, and HBV in donated blood and blood products.

## Reduced risk of transfusion-transmitted infections

While ELISA blood screening technology relies on the detection of serological markers, these markers may not appear in blood until up to three months after an infection, leaving a “window period” in which a risk of transfusion-transmitted infection is increased.

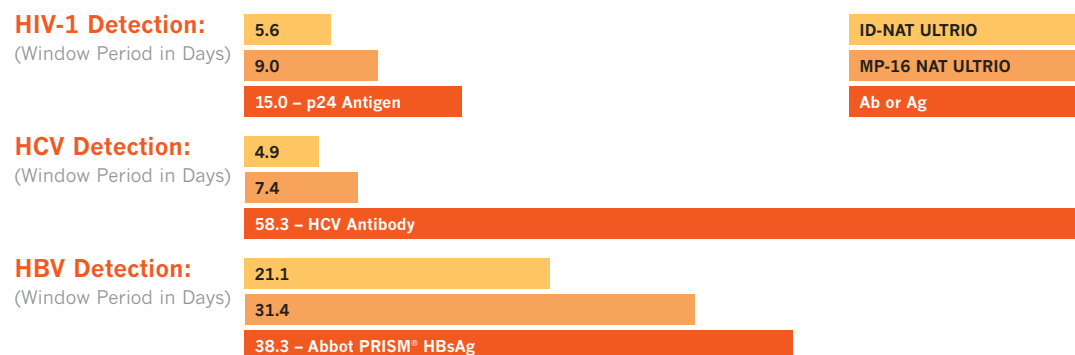
## Optimal nucleic acid testing flexibility and efficiency

The Procleix® ULTRIO® Assay reduces this window period by detecting the presence of the viral RNA or DNA directly.

**Achieve optimal flexibility** with the ability to run ULTRIO® on either the semi-automated Procleix System, ideal for low- to medium-volume laboratories, or the fully automated NAT Procleix® TIGRIS® System for mid- to high-volume laboratories. Procleix ULTRIO allows laboratories to:

- Gain workflow efficiencies when running NAT Procleix® assays on the Procleix TIGRIS System for full automation of NAT.
- Perform multiplex screening and discriminatory NAT on the same Procleix platform.
- Screen donors of whole blood, organ, and tissue all with the same assay; intended usage also includes cadaveric blood samples source plasma, as well as heparinized samples.

**Figure 1:** Scientific models estimate that NAT reduces the infectious window period by 35-91% for HIV-1, HCV, and HBV with individual donation testing (IDT), and by 17 to 87% with mini-pool (pools of 16) nucleic acid testing.<sup>1,2</sup>



**Procleix® ULTRIO® offers exceptional assay performance:**

- Ability to detect HCV genotypes 1-6.<sup>3</sup>
- Redundant detection via primers targeting two highly conserved regions of the HIV-1 gene to help prevent HIV-1 mutant break-through transmissions.<sup>4</sup>

Analytical Sensitivity of the Procleix ULTRIO and Discriminatory Assays on the Procleix TIGRIS System for the Detection of HIV-1, HCV and HBV<sup>3</sup>

Analytical Sensitivity		
Panel Tested	Assay	Detection Probabilities 95% (95% Fiducial Limits)
HIV-1 B copies/mL	ULTRIO Assay	28.8 (25.9-32.7) copies/mL, 47.9 (43.1-54.5) IU/mL <sup>5</sup>
HIV-1 B copies/mL	dHIV-1 Assay	32.1 (28.7-36.7) copies/mL, 53.6 (47.90-61.2) IU/mL <sup>5</sup>
HIV WHO (97/656) IU/mL	dHIV-1 Assay	20.3 (18.1-23.1)
HCV WHO (96/790) IU/mL	ULTRIO Assay	3.0 (2.7-3.4)
HCV WHO (96/790) IU/mL	dHCV Assay	3.2 (2.8-3.6)
HBV WHO (97/746) IU/mL	ULTRIO Assay	10.4 (9.2-12.2)
HBV WHO (97/746) IU/mL	dHBV Assay	8.5 (7.6-9.8)

Specificity of the Procleix ULTRIO and Discriminatory Assays in Normal Blood Donors

Specificity of the Procleix ULTRIO and Discriminatory Assays in Normal Blood Donors <sup>3</sup>				
	ULTRIO	dHIV-1	dHCV	dHBV
Procleix System	100%	99.86%	99.46%	99.73%
Procleix TIGRIS System	99.60%	100%	99.73%	100%

Your Partner  
in Blood Safety

The Procleix® ULTRIO® Assay is another demonstration of Novartis Diagnostics' ongoing commitment to safeguard the global blood supply.

We are proud of our legacy of pioneering research in the field of infectious disease and we will continue to focus on working with leaders and experts to reduce transfusion-transmitted diseases worldwide.

**References**

- 1 Busch, MP, Evolving Approaches to Estimate Risks of Transfusion-Transmitted Viral Infections: Incidence-Window Period Model after Ten Years. Dax EM, Farrugia A, Vyas GN (editors): Advances in Transfusion Safety – Volume IV, Developments in Biologicals (Basel), Basel, Karger, 2007, vol 127, pp 87-112.
- 2 Kleinman SH, Busch MP, Assessing the impact of HBV NAT on window period reduction and residual risk, J Clin Virol 36 Suppl. 1 (2006) S23-S29.
- 3 Data from Procleix ULTRIO Assay Package Insert, 501807 Rev A (US) and 500690EN Rev B (exUS) run on the TIGRIS PROCLEIX System.
- 4 Giachetti, C. et al. Highly Sensitive Multiplex Assay for Detection of Human Immunodeficiency Virus Type 1 and Hepatitis C Virus RNA. J Clinical Microbiology (2002) 40(7):2408-2419.
- 5 Palla et al., Vox Sanguinis, 2006; 90:59-62.

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