Procleix Ultrio Elite Assay

A comprehensive CE-marked assay for your NAT blood screening needs

Available on the NAT fully integrated and automated Procleix Panther system

- Improves blood safety by protecting against infections with HIV-1, HIV-2, HCV, and HBV[1]
- Reduces the risk of TTIs and shortens window periods of HIV-1, HIV-2, HCV, and HBV[1]
- Has comparable sensitivity and specificity to the Procleix Ultrio Plus assay on the Procleix Tigris system for HIV-1, HCV, and HBV[2]

Comprehensive menu of analytes in a single tube assay[1]

- Targets two highly conserved HIV-1 regions to reduce the risk of missed detections
- Includes groups M (subtypes A-H), N, and O
- Includes HIV-2 detection to meet geographic and country requirements
- Includes subtypes A and B (HIV-2)
- Detects HCV genotypes 1-6
- Detects HBV genotypes A-H; target enhancement reagent for optimized HBV detection
- May be used with non-heart-beating cadaveric, source plasma, or heparinized samples
- Is suitable for individual donor testing (IDT) or pools

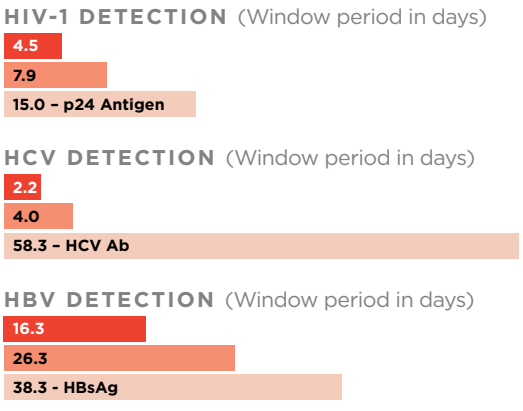
Multicenter data confirms solid assay performance characteristics

- An external evaluation was conducted at multiple centers in France, Italy, and Spain, with all three laboratories achieving comparable results[3]
- Highly sensitive detection was demonstrated across all known genotypes for HIV-1, HIV-2, HCV, and HBV[1]
- Optimal efficiency was demonstrated with only 3 invalid results out of 5,995 samples tested for a low 0.05% invalid sample rate

Significantly reduces window periods with its HIV-1, HCV, and HBV sensitivity[1,4,5]

Window period comparisons are based on Weusten calculation model using 50% detection limits by probit analysis of test results from specific WHO panels and reported in the Procleix Ultrio Elite assay package insert.[1,2,4] Window period comparison may vary based on serology testing methods, variability of WHO panels, testing strategies, and genotypes of the virus in the geographic country of use.

ID-NAT Ultrio Elite
MP-16 NAT Ultrio Elite
Ab or Ag



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Demonstrated specificity

- 99.90% specificity in 8011 fresh and frozen normal blood donor plasma samples[1]
  - Only 8 false positives (0.10% rate)*

100% CLINICAL SENSITIVITY FOR HIV-1, HCV, AND HBV

Clinical sensitivity of the Procleix Ultrio Elite assay in known positive samples[1]				
	All (N = 620)	**HIV-1 (N = 214)**	**HCV (N = 203)**	**HBV (N = 203)**
Diluted (1:16) samples, % (95% CI)	100 (99.4 – 100)	100 (98.3 – 100)	100 (98.2 – 100)	100 (98.2 – 100)

HIV-2 samples were not tested in a 1:16 dilution

INCREASED BLOOD SAFETY THROUGH HIGH ASSAY PERFORMANCE

Detection probabilities (IU/mL)[1]		
Panel tested	**50% (95% fiducial limits)**	**95% (95% fiducial limits)**
HIV-1 WHO (97/650)	5.4 (4.5 - 6.1)	18.0 (15.0 - 23.5)
HIV-2 WHO (08/150)	2.6 (2.3 - 3.0)	10.4 (8.9 - 12.6)
HCV WHO (06/100)	0.9 (0.8 - 1.0)	3.0 (2.5 - 3.9)
HBV WHO (97/750)	0.9 (0.8 - 1.1)	4.3 (3.8 - 5.0)

*Specimens determined to be true positives were repeat reactive in either the Procleix Ultrio Elite assay or the relevant Procleix Ultrio Elite Discriminatory assay. Specimens determined to be false positives were nonreactive upon retesting in either the Procleix Ultrio Elite assay or the relevant Procleix Ultrio Elite Discriminatory assay.

REFERENCES

[1]Procleix Ultrio Elite assay package insert, 503049EN Rev. 002 (exUS).

[2]Deras ML, et al. Performance characteristics of the Procleix Ultrio Elite Assay on the fully automated Procleix Panther Instrument. ISBT Cancun, July 2012.

[3]Sauleda, S. Advances in NAT automation – A Presentation on Novartis Sponsored Trials, July 2012.

[4]Weusten J, et al. *Transfusion.* 2002;42(5):537-548.

[5]Weusten J, et al. *Transfusion.* 2011;51(1):203-215.

IVD

Product registration and availability vary by country.
For more information, ask your local Grifols representative.

Learn more about
Procleix assays at
www.procleix.com

GRIFOLS

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