Procleix® Ultrio Elite Assay

NAT blood screening for HIV-1, HIV-2, HCV, and HBV

Improve blood safety, reduce the risk of TTIs, and shorten window periods[1]

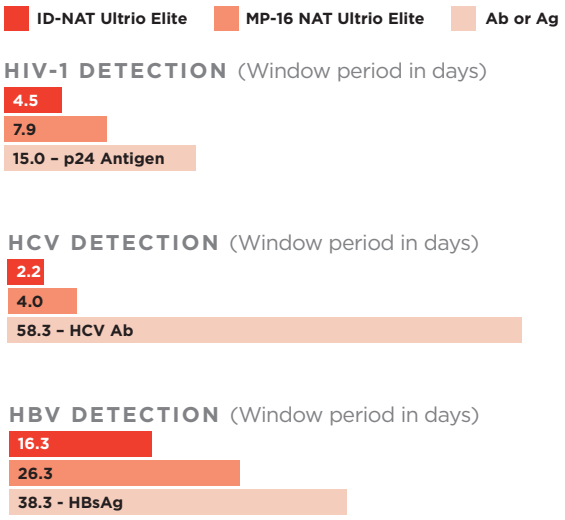
Comprehensive menu of analytes in a single tube assay[1]

- 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
- Includes subtypes A and B
- Detects HCV genotypes 1-6
- Detects HBV genotypes A-H
- 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[1,2]

- Highly sensitive detection was demonstrated across all known genotypes for HIV-1, HIV-2, HCV, and HBV
- Optimal efficiency was demonstrated with only 3 invalid results out of 5995 samples tested for a low 0.05% invalid sample rate

Significantly reduces window periods[1,3,4]



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Procleix® Ultrio Elite Assay

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]

PANEL TESTED	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. 006.

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

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

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

Product registration and availability vary by country.
Ask your local Grifols representative for more information.

Learn more about Procleix assays at
www.diagnostic.grifols.com

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