

Procleix® Blood Screening Solutions

By Gen-Probe and Novartis Diagnostics



One Tube, One Test.

The Procleix® assays are the only blood screening assays utilizing nucleic acid testing (NAT), in which all steps – from extraction through detection – occur in a single tube, helping to protect the integrity of NAT blood screening results.

Transcription Mediated Amplification (TMA) Technology¹

TMA is the patented¹ nucleic acid amplification technology that underlies Novartis Diagnostics leading Procleix® NAT blood screening assays and platforms.

Advantages of TMA

TMA technology allows you to perform NAT blood screening assays with fewer steps than PCR for faster results... without compromising results integrity. Fewer material transfer steps relative to commercialized PCR-based¹ screening methods also means less risk of contamination that can lead to false positive or negative results.³

TMA combined with the Procleix® TIGRIS® System, the only fully integrated and automated NAT blood screening system available today, helps further simplify NAT blood screening and reduce the risks of operator-induced errors such as contamination that can result from manual transfer of samples during the testing process.

How It Works^{3,4,5}

The goal when using an amplification technology is to produce millions of copies of specific target nucleic acid sequences present in a biological sample, often in extremely minute quantities. Following amplification, the copies are sufficient for detection using sophisticated nucleic acid-based probe techniques.

TMA is a transcription-based amplification system that uses two different enzymes to drive the process. The first enzyme is a reverse transcriptase that creates a double-stranded DNA copy from an RNA or DNA template. The second enzyme, an RNA polymerase, makes thousands of copies of the complementary RNA sequence known as the 'RNA amplicon', from the double-stranded DNA template. Each RNA amplicon serves as a new target for the reverse transcriptase and the process repeats automatically, resulting in an exponential amplification of the original target that can produce over a billion copies of amplicon in less than 30 minutes.

The amplicons resulting from this process are then detected by a specific oligonucleotide probe labeled with a chemiluminescent dye.

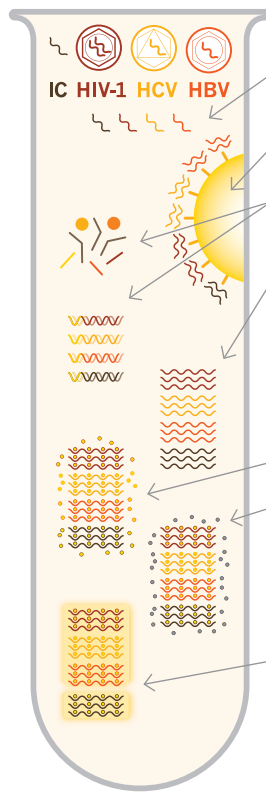
Get the Procleix® advantage today!

One Tube. One Test. Our Procleix® blood screening systems are used to screen more of the 92 million units of blood donated worldwide than any other NAT blood screening system.⁸

One Tube, One Test.
 Transcription
 Mediated Amplification
 (TMA) Technology¹

The overall TMA process is composed of three steps, all of which occur in one tube:^{4,5}

- sample preparation (target capture)
- amplification, and
- detection



- 1 Addition of internal control (IC) and release nucleic acid
- 2 Capture on magnetic microparticle and release of targeted nucleic acid
- 3 Add primers and enzymes
- 4 Amplification reaction
- 5 Add labeled probes to amplified RNA
- 6 Destroy unhybridized labeled probes
- 7 Measure light produced from labels

Confidence in Results

Procleix[®] NAT blood screening solutions are trusted by blood banks worldwide.

- Screen whole blood, plasma, or organ and tissue blood samples for HIV-1, HCV, and HBV in a single simultaneous assay⁶
- Test blood samples from living or cadaveric donors⁶
- Test specimens treated with heparin or other anticoagulants⁶
- Optimal specificity with a unique target capture process that only TMA offers. Targeted nucleic acid is captured via specific probes, ensuring that the starting material to be amplified is less likely to contain non-target nucleic acid sequences that might skew test results.³
- Minimize false positive results. TMA generates an RNA amplicon which is more labile than DNA amplicon outside of the reaction tube, decreasing the risk of laboratory contamination and false positive results.³
- Simplify the amplification process. TMA's isothermic conditions simplify the amplification process, making it amenable to full automation via the Procleix[®] TIGRIS[®] System.³
- Sensitivity of discriminatory assays is comparable to the screening assay to help to further support the highly reliable results.⁷

References

- 1 The state-of-the-art TMA technology was developed by Gen-Probe, Inc., our partner for NAT innovation. TMA is also used extensively and proven in Gen-Probe's line of in vitro diagnostic products.
- 2 cobas TaqScreen MPX Test Package Insert, Doc Rev. 3.0, February 2009.
- 3 Hill C, "Gen-Probe Transcription-Mediated Amplification: System Principles," Gen-Probe Incorporated, URL: www.gen-probe.com.
- 4 Gen-Probe, Inc. URL: http://www.gen-probe.com/science/
- 5 Giachetti C, et al. Journal of Clinical Microbiology, July 2002, p. 2408-2419.
- 6 Procleix Ultrio Package Insert, Rev. 500690, Rev. B, May 2009.
- 7 M. Phillips et al. (LifeSource) "Analysis of Unresolved Discriminatory Test Results Using the cobas TaqScreen MPX Assay and cobas AmpliScreen HIV, HCV, and HBV tests"; AABB, Baltimore, October 2010.
- 8 Novartis Diagnostics data on-file.

This material may only be used in jurisdictions where the product(s) and/or indications mentioned in the material are approved. For a complete list, visit www.novartisdiagnostics.com/approvals.



United States office:
 Novartis Vaccines & Diagnostics, Inc.
 4560 Horton Street
 Emeryville, CA 94608 USA
 Tel: (800) 452-6877

Asia/Pacific office:
 Novartis Vaccines & Diagnostics (HK) Ltd.
 Units 1506-07 DCH Commercial Centre
 25 Westlands Road Quarry Bay, Hong Kong
 Tel: +852 2161 3100

European office:
 Novartis Vaccines & Diagnostics Svcs. AG
 Lichtstrasse, 35
 4056 Basel, Switzerland
 Tel: +41 61 69 62 288