

## **HCV Assay – Intended use**

The PROCLEIX® HIV-1/HCV Assay\* is a qualitative in vitro nucleic acid amplification test for the detection of human immunodeficiency virus type 1 (HIV-1) RNA and/or hepatitis C virus (HCV) RNA in human plasma specimens from individual blood donors, including donors of whole blood and blood components, source plasma and other living donors.

It is also intended for use in testing plasma to screen organ donors when specimens are obtained while the donor's heart is still beating, and from blood specimens from cadaveric (non-heart-beating) donors.

It is not intended for use on samples of cord blood.

The assay is intended for use in screening individual donor samples of all specimen types, or pools of human plasma comprised of equal aliquots of not more than 16 individual donations for donors of whole blood, blood components, or source plasma.

This assay is intended to be used in conjunction with licensed tests for detecting antibodies to HIV-1 and HCV.

This assay may be used as an alternative to licensed HIV-1 p24 antigen tests for screening human plasma from donations of whole blood and blood components.

### Summary and Explanation of the Test

The PROCLEIX Assay utilizes target amplification nucleic acid probe technology for the detection of HIV-1 RNA and HCV RNA in voluntary blood donors. The assay contains reagents that may be used for simultaneous detection of both viruses or the individual viruses. The PROCLEIX® Assays incorporate an Internal Control for monitoring assay performance in each individual specimen.

The PROCLEIX HIV-1/HCV Assay involves three main steps, which take place in a single tube:

1. Sample Preparation
2. HIV-1 RNA and HCV RNA target amplification by Transcription-Mediated Amplification (TMA)
3. Detection of the amplification products (amplicon) by the Hybridization Protection Assay (HPA)

*\* Developed and manufactured by Gen-Probe Incorporated. Distributed by Novartis Vaccines and Diagnostics, Inc.*