

## HCV Assay – Performance Characteristics

- Pivotal trial for PROCLEIX® HIV1/HCV Assay conducted at 6 U.S. study sites in September and October 2000
- Study compared PROCLEIX HIV1/HCV Assay and HIV-1 and HCV discriminatory assays with serological assays in three clinical lots
- Clinical studies included:
  - Analytical and clinical sensitivity studies
  - Specificity studies in normal donor specimens
  - Non-specificity studies in high-risk populations
- BLA submitted CBER on Jan. 9, 2001; received approval on Feb. 27, 2002
- PROCLEIX HIV-1/HCV Assay and HIV-1 and HCV discriminatory assays detected these viral subtypes at 100 and 300 copies/mL:
  - HIV-1 subtypes
    - Group M - Subtypes A, B, C, D, E, F, G
    - Group N
    - Group O
  - HCV subtypes 1, 2\*, 3, 4, 5, 6

\* 13/13 were reactive at 300 copies/mL, 12/13 were reactive at 100 copies/mL when tested with PROCLEIX HIV1/HCV Assay.

- Excellent sensitivity and specificity

		<b>Sensitivity (%)</b>	<b>Specificity</b>
PROCLEIX® HIV-1/ HCV Assay	16-member pool	99.3	99.67
	Individual Donation	99.8	99.87
HIV-1 Discriminatory	Individual Donation	100	99.76
HCV Discriminatory	Individual Donation	99.6	99.71

### References

1. PROCLEIX HIV-1/HCV Assay package insert.
2. Linnen JM, Gilker JM, Menez A, et al. Sensitive Detection of Genetic Variants of HIV-1 and HCV with an HIV-1/HCV Assay Based on Transcription Mediated Amplification. J Virol Methods. April 2002;102:139-155.

*PROCLEIX is a trademark of Novartis Vaccines and Diagnostics, Inc.*