

Reinventing blood safety

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Comparative Study of 3 NAT Assays: Procleix, Extractor/AmpliScreen, Multiprep/AmpliScreen

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Objectives:

The goal of this study was to assess sensitivity and operational feasibility of 3 Nucleic Acid Testing (NAT) assays: Procleix HIV-1 / HCV Assay (Gen-Probe / Chiron Blood Testing), Cobas AmpliScreen HIV-1 test version 1.5 and HCV Test version 2.0 (Roche Diagnostics) with 2 different procedures of sample extraction; Multiprep (Roche Diagnostics) and NucliSens Extractor (BioMérieux).

Design:

The comparative study was conducted in the same laboratory on the same panels. Each assay has been implemented according to similar conditions as routine use and in compliance with manufacturer's instructions.

Materials:

The panels used to assess analytical sensitivity were WHO International Standards for HCV and HIV-1 NAT Assays, PeliCheck HCV-RNA genotype 1 and 3 panels and PeliCheck HIV-1 RNA genotype B and E panels (CLB). For clinical sensitivity investigation, HIV-1 and HCV seroconversion panels from Bio Clinical Partner and for genotypes detectability, panels from Boston Biomedica Inc. and Walter Reed Army Institute of Research were used.

Results:

The 95% detection level for HIV-1 and HCV for Procleix and Extractor/Ampliscreen Assays were similar (18 IU/ml for HIV-1 and 3 IU/ml for HCV). Detection levels were significantly different for the AmpliScreen when used with a Multiprep extraction step and compared to the two other procedures. HCV genotypes 1, 2, 3, 4, 5, 6 and HIV-1 subtypes A, B, C, D, E, F were detected by the 3 assays but HIV-1 group O was detected only with Procleix. For operational feasibility, higher productivity and throughput are obtained with Procleix (100 samples tested in 5 hours instead of 10 samples in 6 hours for Extractor/AmpliScreen and 24 samples in 7 hours for Multiprep/AmpliScreen).

Conclusion:

Procleix and Extractor/ Ampliscreen showed similar performance in terms of sensitivity, but the Procleix productivity was higher for blood donor screening.