

EVALUATION OF A MULTIPLEX ASSAY FOR HCV / HIV-1 / HBV NAT SCREENING IN THE NETHERLANDS

M. Koppelman; H. Reesink; M. Sjerps and H.T. Cuyper
Sanquin Diagnostic Services – Amsterdam

Objective:

In Sanquin, blood donations are currently screened by NAT for HIV and HCV in pools of 8. Sanquin is now assessing the introduction of HBV DNA testing. For this purpose the evaluation of the Procleix Ultrio Assay was performed.

Materials and Methods:

Dilution series of WHO International Standards for HBV, HCV and HIV and commercial reference panels for HBV-DNA genotype A, HCV-RNA genotype 1 and HIV-1 RNA genotype B (PeliCheck, Sanquin-VQC) were tested in 24 replicates. For HBV genotype detection, dilution of genotypes A to G samples were used. Robustness was evaluated by screening of 8,800 donations in pools of 8.

Results:

Analytical sensitivity: concentration of the target for 95 % success rate of detection (95 % CI) as determined by Probit analysis with log conversion of concentrations.

Panel	HBV-DNA	HCV-RNA	HIV-1 RNA
WHO-IS in IU/ml	9.0 (6.0-15)	3.0 (2.0-5.0)	32 (15-111)
PeliCheck in geq/ml	313 (186-686)	101 (61-212)	89 (47-235)

All genotypes were detected at 100 geq/ml or better. No false positive result was found and 99.9% of the results were valid.

Conclusions: Based on the 95 % limit of detection, the probabilities of detecting HBV DNA, HCV-RNA and HIV-RNA for the individual donation when present in a pool of 8 are respectively 72 IU/ml, 24 IU/ml and 256 IU/ml. HBV genotypes (A-G) are detected with comparable sensitivity. The assay proved to be robust. Conversion of the routine testing from pools of 48 to pools of 8 might be done with a limited expansion of workload.