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

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

Objective:

In Sanquin, blood donations are currently screened by NAT for HIV-1 and HCV in pools of 48. Sanquin is now assessing the introduction of HBV DNA testing. For this purpose the evaluation of the Procleix Ultrio Assay was performed.

Materials & Methods:

Dilution series of WHO International Standards for HBV, HCV and HIV-1 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.