Rode Kruis Vlaanderen

THE COBAS MPX ASSAY ON THE COBAS 6800 PLATFORM: DIAGNOSTIC PERFORMANCE AND ONE-YEAR ROUTINE EXPERIENCE

I. Debruyne, E. De Samblanx, M. Vanbrabant, A. Muylaert, E. Lazarova

Background: In most countries, blood donations are routinely screened for the presence of HIV, HBV and HCV by nucleic acid testing (NAT). Previous assays were based on the simultaneous detection of viruses, requiring an additional step for discrimination. The introduction of discriminatory NAT assays, combined with a new generation of diagnostic platforms, has resulted in an increased throughput, an ameliorated user friendliness and an improved donor management. One of the new assays, the cobas MPX assay on the Roche cobas 6800 platform, allows discriminatory detection of HBV-DNA, HCV-RNA, HIV-1 Group M RNA, HIV-2 RNA and HIV-1 Group O RNA in human plasma and serum samples.

Aims: We aimed at studying the diagnostic performance of the cobas MPX assay on the cobas 6800 system in comparison with the cobas Taqscreen MPX v1 assay on the cobas s201 system.

Methods: During pre-implementation verification, the diagnostic specificity was determined by testing 280 minipools of 6 donations (MP6) with the cobas Taqscreen MPX v1 assay and the cobas MPX assay in parallel. To assess diagnostic sensitivity, a total of 18 samples reactive for HBV, HCV or HIV were tested with the cobas MPX assay, both individually and in MP6. The limit of detection (LoD) was determined by Probit analysis using a WHO reference standard or an equivalent Roche material. We also implemented the cobas Synergy software, a middleware that connects the Hamilton STAR pooling instrument, cobas 6800 system and laboratory information system and manages the total workflow. One year after the implementation of the assay in January 2017, a total of 369.048 donations had been tested in minipools. To investigate long-term reproducibility, the inter-run precision was calculated for the cycle treshold values of all the assay controls measured during one year.

Results: In the pre-implementation verification, the diagnostic specificity and sensitivity were both 100%. The 95% LoD of HBV, HCV, HIV-1M, HIV-2 and HIV-1O was 1.1, 6.6, 21.9, 4.4 IU/mL and 5.6 cp/mL, respectively. Since the implementation of the assay, 11 samples were NAT reactive when tested individually. Ten of these results were confirmed by serological testing or by NAT testing in an external laboratory, one result was false-positive (99.9997% specificity). However, we also observed 79 pools that were initially reactive, but did not have a reactive result when tested individually. It is likely that these non-resolved pools are caused by non-specific amplification and are thus false-positives, which lowers the specificity to 99.87%. Long-term %CV's are 2.02, 1.10, 0.98, 0.96, and 1.11 for HBV, HCV, HIV-1M, HIV-2 and HIV-1O, respectively. Since we are the first user of the Synergy software, we frequently encounter teething problems, hampering the workflow.

Summary/Conclusions: The cobas MPX assay on the cobas 6800 shows high analytical and diagnostic sensitivity and good reproducibility. During routine testing we regularly observe reactive pools that cannot be resolved on the individual level, lowering the initial diagnostic specificity of 100% to 99,87% for MP6. Furthermore, the Synergy software currently does not deliver added value compared to its predecessor. These are limitations for which we advise an improvement.