

HCV, HIV-1, HBV MOLECULAR SCREENING FOR BLOOD DONATION: FROM SEMI-AUTOMATE SYSTEMS TO THE FULLY AUTOMATED INSTRUMENT PLATFORM (P-127)

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Background: Since 1998 we experimented with the innovative technologies for blood screening based on detection of viral genomes. At the beginning two assays were available: the PCR based HCV Cobas Ampliscreen System (Roche) for screening pooled plasma and the TMA duplex HCV-HIV1 Procleix (Gen-Probe) for screening individual donations. Both the procedures, were initially available in a semi-automate format. Afterwards the multi-test to detect simultaneously HCV-HIV1 and HBV were developed and recently the TIGRIS[®] instrument platform for fully automating HCV-HIV1-HBV nucleic acid testing (NAT) has become available.

Aim: The goal of this work is to compare the operational feasibility of the semi-automate systems Multiprep HCV-HIV1-HBV Cobas Ampliscreen, Multiplex PROCLEIX[®] ULTRIO[®] Assay with the fully automate PROCLEIX[®] TIGRIS[®] platform.

Methods: Each assay has been implemented as routine use and performed in compliance with the manufacturer's instructions. Cobas Ampliscreen system has been used for screening plasma mini-pool of 20 samples. The pooling system includes Tecan Genesis with PMS software for pool management operating with the AmpliPool software for the traceability of specimen-pool linkage and the transfer of NAT results from pool to individual specimens. The multiplex PROCLEIX[®] ULTRIO[™] Assay both in semi-automate and fully automate TIGRIS system has been used for screening individual donations.

Results: Both the semi-automate systems require separated pre and post amplification area and several manual steps by a proficient technologist with risks in terms of operator safety and operator errors. By using Cobas Ampliscreen all the samples undergoing NAT screening need to be available before starting the procedure, whose length is ranging between 6-9 hours based on the daily workload. Up to 360 samples can be loaded on each Cobas AmpliCor if a single instrument is dedicated for each virus detection. The turn around time (TAT) to release blood units is generally 24 hours from blood collection. The Multiplex Procleix Ultrio manual format requires 1 operator to process up to 180 samples. For more samples at least 2 operators are required. No transfer from sample tube to assay tube is necessary. The entire procedure lasts about 5 hours and the TAT is 12/24 hours depending on sample time arrival. An additional discriminatory assay is required in case of initial reactivity. The fully automate TIGRIS system is intended for high sample throughput allowing to load in each worklist up to 500 samples. The instrument set up requires about 1 h. Following reagent and sample loading, according to bracket or work-list run configuration, the instrument is a walk-away automation, only periodic MTU loading being required (100 tubes for each loading). The length of the treatment ranges from 5 hours for 100 samples up to 14 hours for 1000 samples. The TAT could be between 5 to 24 hours from collection.

Conclusion: Based on our experience, in comparison with the semiautomate systems the operational feasibility of fully automate TIGRIS platform allows high productivity and throughput with a system flexibility which allows to process the samples according to the site need.