
IMPLEMENTATION OF PROCLEIX® TIGRIS® SYSTEM FOR NUCLEIC ACID TESTING OF THE BLOOD DONATIONS IN A TRANSFUSION CENTER (P-293)

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BACKGROUND

In July 2006, the Transfusion Center of the Valencian Community, started the simultaneous detection of the RNA-HCV, RNA-HIV1 and DNA-HBV on individual donations by the PROCLEIX TIGRIS System that automates the extraction, amplification and detection of viral nucleic acids. The aim of the work is to study the results of the implementation of this technology in our center, taking into account reliability, workflow and specificity.

METHODS

The period of study was from July 2006 to December 2006. The configuration of the PROCLEIX TIGRIS System used in our center consisted of three TIGRIS instruments. Two work shifts were implemented. All the blood donations were analyzed by the PROCLEIX® ULTRIO® Assay (Chiron corp.) for the joint detection of RNA-HCV, RNA-HIV1 and DNA-HBV by genomic amplification with TMA (transcription mediated amplification-based assay). The initially reactive results were repeated by the same method, both the initial tube as well as an aliquot of buffy-coat. The repeatedly reactive donations were tested by PROCLEIX Discriminatory assay (Chiron Corp.) to detect the different virus in the TIGRIS instruments. Each of worklists contained a max of 172 samples, three calibrators and three controls for each of viral genomic markers, one negative calibrator and one negative control.

RESULTS

- A total of 84226 blood units in 710 worklists were analyzed in six months.
- Workflow: N° blood units/day: 533; time of processing/day: 7 h; time of maintenance/ day: 2h 30m
- N° nonvalid worklists: 32 (calibrators errors: 9; mechanicals errors: 7; control errors: 11; internal control errors: 5)
- N° nonvalid samples: 297 (sample errors: 16; internal control errors: 60; level verification errors: 46; reagent dispensation errors: 46; pipetator movement errors: 57; luminometer errors: 45; MTU's read errors: 25)
- N° initially reactive units: 293; n° repeatedly reactive units: 63; n° NAT-HBV: 29; n° NAT-HCV: 24; n° NAT-HIV1: 8; n° discriminatory test negative units: 2
- Discordance cases found between the serological and NAT tests for HBV: 5 N° HBsAg negative/ NAT-HBV positive: 4 (3 occult hepatitis, 1 window period) and n° HBsAg positive / NAT-VHB negative: 1

CONCLUSIONS

1) The workflow implies two shifts of work being adjusted to processing times in our Transfusion Center. 2) A 0.35% of the total units were initially reactive. 3) A 20.8% of the initially reactive units were positive to some of the viral genomic markers by discriminatory tests. 4) There were a 0.35% of nonvalid samples. 5) All the positive results by NAT also were positive by screening serology markers except the 4 discordance cases of HBV. 6) One sample was detected by HBsAg screening test and was not detected by NAT-HBV test. 7) The yield obtained with the introduction of NAT-HBV is of 1:84226, as opposed to an expected yield of 1:241546 in Spain.