OP 18: Evaluation of the Cobas MPX Assay on the Cobas 6800 instrument and the grifols procleix ultrio elite on the panther instrument

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Introduction

The South African National Blood Service (SANBS) implemented ID-NAT testing in October 2005 using the Grifols Procleix ™ULTRIO assay (Ultrio) and since 2010 the ULTRIO Plus (Plus); both on the Tigris instrument. New NAT systems currently available are the Grifols ULTRIO Elite assay (Elite) on the Panther instrument and the Roche MPX assay available with two instruments (Cobas MPX6800 and MPX8800). A head to head evaluation was performed due to limited available data and aimed to evaluate of sensitivity, specificity, NAT yield rate, invalid test rate, failed run rate and mean time between failures.

Methods

An additional sample was drawn on all donors that successfully donated blood in the Vaal zone. Samples were tested by MPX assay on the Cobas 6800 and the Elite assay on the Panther instrument and compared to the current Plus assay on Tigris platform. Specificity, NAT Yield and Non-repeat reactive (NRR) rates were calculated from 3638 and 3815 tests on MPX and Elite respectively.

Doubling dilutions (1:1 to 1:64) were prepared from 10 concordant positives (pre-diluted to 300 cp/ml), 15 NAT yields (HCV only 7) and SANBS QCs (12 replicates) and tested for HIV, HBV and HCV. Serology Yields and external dilution panels (BioQControl) were tested in 12 and 24 replicates respectively.

Sensitivity was reported using the total number of reactive results from the panels as the numerator and the total number of replicates tested as the denominator.

Invalid rate (Invalid results/Total samples tested), failed run rate (Failed runs/Total runs) and mean time between failures (MTBF) (Total uptime/Breakdowns) were calculated.

Results

Specificity was reported as 99.94%, 99.97% and 99.98% for MPX, Elite and Plus respectively. No additional HIV and HCV Yields were detected. The HBV yield rates were 0.11%, 0.03% and 0.05% for MPX, Elite and Plus respectively. Invalid test and failed run rate were 1.85% and 3.08% and 4.23% and 14.52% on Panther and Cobas respectively ($p<0.05$). The Cobas had a MTBF of 171 hours compared to 396 hours on Panther.

Cross-reactivity was observed on MPX test with 51.61% potential false reactivity amongst all HIV and HCV panel samples. No cross-reactivity was observed in HBV samples or on Elite.

Discussion

There was no difference in specificity and NAT Yield rate using MPX, Elite and Plus. The invalid test and failed run rate was significantly higher ($p<0.05$) on the Cobas raising a concern in terms of reliability. The Panther system uses significantly more reagents for calibrators. The MTBF on the Cobas relates to a breakdown once a week per instrument impacting on turnaround time compared to Panther that relates to one breakdown every 14 days per instrument. The MPX assay was more sensitive for HBV DNA detection ($p<0.05$) and will potentially detect additional HBV infections. The cross-reactivity observed will however complicate confirmatory algorithms and donor notification and might require a second NAT system.

Based on the results in this evaluation the Panther system was recommended for use by SANBS.