

QUALITY CONTROL PROGRAMME FOR NUCLEIC ACID SCREENING IN BLOOD SERVICE LABORATORIES.

Jardine D, Dent BRJ, Pham T, Dimech W, and Dax EM.

National Serology Reference Laboratory, Australia, Fitzroy, AUSTRALIA

Background The National Serology Reference Laboratory, Australia (NRL™) provides Quality Assurance (QA) Programmes to blood screening laboratories that perform nucleic acid testing (NAT) for HIV-1, HCV and HBV. They also allow laboratories to follow the precision and accuracy by peer group comparison of their test results. The quality assurance programme monitors test kit performance through quality control (QC) programmes. Thus laboratory and assay performance are monitored continuously.

In order to better manage QC and specificity monitoring results received from laboratories, NRL has developed an internet-based application EDCNet which allows laboratories to immediately assess run performance. Currently fourteen laboratories are performing nucleic acid screening with the Chiron TMA assays and participating in NRL's QC programme. Seven laboratories screened blood donations using the Chiron Procleix HIV-1/HCV TMA assay and seven are using the Chiron Ultrio HIV-1/HCV/HBV TMA assay, three of which use the Tigress system.

The laboratories were located in Australia (5), New Zealand (2), Singapore (1), Europe (3) and South Africa (3).

Methods Participants were supplied with three QC samples (HCV RNA: 380 geq/ml, HIV RNA: 250 geq/ml, HBV DNA 1000 geq/mL (Acrometrix VQC, The Netherlands) and normal human plasma to monitor run-to-run sensitivity and specificity of the TMA assays. The three nucleic acid positive samples were secondary working reagents calibrated to the WHO International Standards for HIV and HCV. QC samples were run as a Go/No Go controls in every assay run. Results were submitted to the NRL through EDCNet (<https://www.nrlqa.net>), Data were analysed and summary statistics presented in regular reports, accessed through the NRL website.

Results Between September 2001 and February 2006 participants submitted in excess of 50,000 QC results from 27 different QC sample batches. Analysis of the data from the latest QC sample batches PS010505 (HCV), PS020505 (HIV) and PS121203 (HBV) (n = 4,850) showed that from 2,264 assay runs, only 1 (0.04%) was invalidated on the basis of a non-reactive QC sample. Inter-laboratory precision, estimated by coefficients of variation (CV), ranged from 4.06 – 18.57%. (Procleix), 3.91 – 11.10%. (Ultrio) and 8.85 – 28.97%. (Ultrio-Tigress). Luminometer-specific trends were demonstrated graphically in EDCNet. Not all laboratories routinely include a negative run control with every run. Of the 5,475 runs which included the normal human plasma run control, only 1 (0.02%) was invalidated on the basis of a reactive QC sample

Conclusions: Changes and trends in results of testing positive QC samples, in the Chiron TMA assays, allowed potential problems, such as the need to monitor luminometer performance, to be identified.