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QUALITY CONTROL PROGRAM FOR NUCLEIC ACID SCREENING IN BLOOD SERVICE LABORATORIES

Author:	D.K. Jardine, National Serology Reference Laboratory, Fitzroy, Australia
Co-author: (s):	B.R.J. Dent, National Serology Reference Laboratory, Fitzroy, Australia S. Read, National Serology Reference Laboratory, Fitzroy, Australia C. Hyland, Australian Red Cross, Brisbane, Australia E.M. Dax, National Serology Reference Laboratory, Fitzroy, Australia

Background

Recent developments in technology have seen the introduction of Nucleic Acid Testing (NAT) to screen for early infection with HIV or HCV in blood donors. The National Serology Reference Laboratory (NRL) implemented a quality assurance (QA) programme for laboratories using these technologies. QA methods used by the NRL include Quality Control (QC) and External Quality Assessment Schemes.

Ten laboratories participate in NRL's QC programme, performing nucleic acid screening with the Chiron TMA Multiplex assay (TMA). The laboratories are located in Australia, New Zealand, South east Asia and Ireland. A further 7 laboratories from Korea and Poland are expected to begin participation in this programme early 2005.

Materials and Methods

Participants were supplied with three QC samples (HCV RNA: 380 geq/ml, HIV RNA: 250 geq/ml and normal human plasma) to monitor run-to-run sensitivity and specificity of the TMA assays. The two RNA positive samples were produced by the Viral Quality Control Laboratory (now Acrometrix VQC) in The Netherlands and 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 and the results submitted to the NRL through the NRL's on-line QC interface, EDCNet (www.nrlqa.net), which allows laboratories to immediately assess run performance. Data were analysed and summary statistics presented in regular reports, accessed through the NRL website.

Results

Between September 2001 and February 2005 participants submitted in excess of 40,000 QC results from a number of QC sample batches. Analysis of the data from the QC sample batches hivspy004 and hcvsy004 (n = 11,772) showed that from 5615 assay runs, 13 (0.23%) were invalidated on the basis of a non-reactive QC sample. Analysis of the data from the subsequent HIV and HCV QC sample batches 005 and 006 (n = 15,946) showed that none of the 7973 assay runs was invalidated on the basis of a non-reactive QC sample. Inter-laboratory precision, estimated by coefficients of variation (CV), ranged from 7.92 - 17.10%. Accuracy of the results was estimated by calculating bias, which highlighted luminometer-specific trends that were demonstrated graphically in EDCNet.

Discussion

Changes and trends in results of testing two RNA positive QC samples, in the Chiron TMA Multiplex assay, allowed potential problems, such as the need to monitor luminometer performance, to be identified.