

## DOES A HIGH RESULT FOR A QUALITY CONTROL SAMPLE INDICATE A HIGHER FALSE REACTOR RATE IN THE ABBOTT PRISM ASSAYS USED FOR BLOOD DONOR SCREENING?

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### Background

The National Serology Reference Laboratory, Australia (NRL), coordinates a Quality Control (QC) programme for 22 laboratories that screen for anti-HIV 1&2, anti-HCV, HBsAg and anti-HTLV I/II using the Abbott PRISM assays. The NRL also collects information that allows the repeat reactor rates (specificity) of each assay to be calculated and these are compared between laboratories and reagent lots.

### Aim

To establish a correlation between QC sample results and the level of false reactor rates in PRISM assays in order to assess if there is mutual prediction of assay problems.

### Methods

Three different production batches of the same multi-marker QC sample 'PeliSpy s2058 Type 7' (QC), produced by VQC-AcroMetrix (The Netherlands), were provided to 7 laboratories between October 2003 and March 2006. Laboratories tested the QC each day and reported results including the run date, PRISM reagent lot used and Sample:Cut off ratio (S:Co) for each PRISM assay. In the same time period the 7 laboratories reported the number of specimens screened each week by assay and PRISM reagent lot, as well as the number of initially and repeatably reactive specimens and the number confirmed positives. Results from QC samples and information collected for specificity monitoring were submitted using the NRL's internet-based application EDCNet (<https://www.nrlqa.net>).

The mean S:Co ratio for each PRISM reagent lot was calculated for each batch of QC. The repeat reactor rate (RRR) for each PRISM reagent lot was calculated as the proportion of negative specimens that were initially reactive and remained reactive on one or two tests on retesting in duplicate. The mean S:Co ratios for each QC batch were compared with the RRR for each PRISM reagent lot. Correlation coefficients (r) were calculated (Sigmaplot) for linear regression analyses.

### Results

A total of 59,685 QC results, reported using 202 different PRISM reagent lots (80 anti-HIV, 51 anti-HCV, 36 anti-HTLV and 35 HBsAg), were analysed. Specificities were calculated from the screening results of approximately three million specimens.

Twelve regression analyses were performed on the data for each of the four PRISM assays and each of the three QC batches. The anti-HIV 1&2, anti-HCV and HBsAg reagent lots showed no significant correlation between reactor rates and changes in QC S:Co ratios. The anti-HTLV I/II reagent lots showed a significant correlation for only one of the three QC batches.

### Summary

Only one of the 12 analyses showed a significant correlation between higher QC sample S:Co ratios and an increased RRR. This study showed that higher QC S:Co ratios are not usually associated with an increased RRR on the Abbott PRISM assays. Therefore changes in PRISM assay specificity do not appear to be a major contributing factor to changes in the S:Co ratio values of QC samples.

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