

VARIATION IN THE PERFORMANCE OF REAGENT BATCHES OF THE ABBOTT ARCHITECT HIV AG/AB COMBO CMIA DETECTED IN AN INTERNATIONAL QUALITY CONTROL PROGRAMME

Pham T¹, Dimech W¹, Karakaltsas M¹, and Dax EM¹

¹ *National Serology Reference Laboratory, Australia*

Background: The National Serology Reference Laboratory, Australia (NRL) coordinates a quality assurance (QA) programme for laboratories testing for blood-borne or sexually transmitted infections. The QA programme includes external quality assessment schemes (EQAS) and quality control (QC), which monitor assay performance.

Aims: (a) To investigate a reduction in QC sample reactivity associated with some reagent batches of the Abbott ARCHITECT HIV Ag/Ab Combo CMIA (Architect HIV). (b) To determine whether a comparable reduction in reactivity was observed in EQAS sample results obtained from testing in the same reagent batches.

Method: Participants were provided low positive QC samples (PeliSpy Multimarker, AcroMetrix, CA, USA). The QC samples were stock standards positive for HBsAg, anti-HIV-1, anti-HCV and anti-HTLV-I, diluted in defibrinated normal human plasma. Participants were instructed to test a QC sample in addition to testing the controls provided with the assays. The NRL provided each participant with access to the NRL's Internet-based QC program, **EDCNet** (<https://www.nrlqa.net>) for the entry and analysis of their QC sample test results. QC sample results submitted to **EDCNet** between 1 January 2006 and 2 December 2007 were analysed by the NRL to review assay performance. In the third HIV EQAS challenge for 2007, participants tested ten undiluted plasma samples, six of which were HIV-1 positive. Results were also investigated for these six HIV-1 positive samples tested in different reagent batches of the Architect HIV. Results were expressed as sample:cutoff ratios (S:Co).

Results: Over the period, QC samples were tested in 62 Architect HIV reagent batches. QC samples PeliSpy Multimarker Type 38, batches 0612801 and 0633401 were tested in 39 (n= 3041, mean S:Co = 3.52) and 36 (n=2415, mean S:Co=3.85) Architect HIV reagent batches respectively. PeliSpy Multimarker Type 4, batch 0605201 was tested in 18 reagent batches (n=1927, mean S:Co= 7.63). QC sample results showed reduced reactivity in eight of the 62 reagent batches. The S:Co for QC samples Types 38 and 4, in the affected Abbott HIV reagent batches, ranged from 2.01 to 2.77, and from 3.84 to 4.65, respectively. Similar reductions were not detected in the assay controls or in an external HIV-1 p24 antigen control. Seventy-eight EQAS test results obtained in ten reagent batches of Architect HIV were reported for each of the six HIV-1 positive EQAS samples investigated (total = 468 results). Of these, 90 test results obtained in three Architect HIV reagent batches showed reductions in S:Co when compared with the remaining results for corresponding samples. Each of these three reagent batches was one of the eight in which lower QC sample results had been observed.

Summary: A reduction in reactivity in QC sample test results associated with Architect HIV reagent batches was detected by multiple laboratories participating in the NRL's QC programme, and this prompted an investigation. A similar reduction in reactivity was detected in results for undiluted HIV-1 positive EQAS samples but not in the assay controls. These findings highlight both the importance of testing and monitoring the results of an independent internal QC sample and that of participating in EQAS.