

AN INVESTIGATION OF ABERRANT HIV EXTERNAL QUALITY ASSESSMENT SCHEME RESULTS

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Background: The National Serology Reference Laboratory, Australia (NRL) coordinates an External Quality Assessment Scheme (EQAS) for HIV. The panels are distributed three times yearly to laboratories in Australia and internationally. The first panel distributed for 2007 (HIV Serology EQAS Panel ID 2007/Apr/03) consisted of five samples that were negative and five samples that were positive for anti-HIV. All ten samples were negative for HIV p24 antigen. One participant obtained reactive results for all ten samples in the EQAS panel (some low and some high) using the Abbott Architect HIV antigen/antibody CMIA. The pattern of results was suggestive of sample carry-over on the Architect instrument. The instrument had recently undergone scheduled preventative maintenance.

Aims: To determine the cause of the aberrant HIV EQAS results obtained by the participant.

Methods: Three principal measures were taken to investigate the aberrant results:-

- Panel samples from the participant were swapped with those from another laboratory participating in NRL's HIV EQAS;
- NRL provided three additional panels A, B and C to the participant, that were constructed so that results of their testing would confirm whether or not carry-over was occurring. In Panel A the negative samples' IDs were 1-5, the positives' 6-10. Panel B, was constructed to have two aliquots of the same negative sample following each of three of the positive samples. The participant was instructed to test the samples in Panel A and then Panel B in order and in the same "run". Panel C was a replicate of EQAS panel 2007/Apr/03.
- Service personnel from Abbott examined the instrument on two occasions.

Results: The results of testing of Panels A and B confirmed sample carryover:

- When negative samples preceded positive samples, negative results were obtained for the negative samples
- When negative samples followed positive samples, the negative samples were falsely positive and there was a dilution effect observed in the results for sequential negative samples.

Following continued aberrant results for negative samples in Panel B, Abbott service personnel replaced the sample probe and a valve in the wash station of the Architect instrument. The participant then tested Panel C and obtained results that agreed with the reference results for the panel.

Summary: The participant's laboratory services a population with a low prevalence of HIV and relies on participation in EQAS to confirm its ability to detect anti-HIV positive samples. An investigation revealed that an instrument related problem was causing sample carry-over. The problem was corrected after the sample probe and a valve in the wash station were replaced. Before this, a scheduled service to the Architect instrument had been carried out but it was not detected that sample carry-over was occurring.

This case study highlights:

- The importance of EQAS participation in providing samples not routinely encountered;
- That scrutiny of EQAS results provides an early warning mechanism to detect problems;
- The importance of equipment maintenance;
- The importance of ensuring the recommended maintenance is performed;
- The importance of a planned approach to troubleshooting.