EXTERNAL QUALITY ASSESSMENT OF HLA-B*57:01 TYPING FOR PROSPECTIVE ABACAVIR PATIENTS

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Introduction

Hypersensitivity reactions to abacavir, a HIV-1 nucleoside-analogue reverse-transcriptase inhibitor, are strongly associated with possession of B*57:01 in white and black HIV/AIDS patients. Current HIV treatment guidelines recommend B*57:01 testing of patients who may require abacavir.

The UK National External Quality Assessment Service for Histocompatibility and Immunogenetics (UK NEQAS for H&I) have operated a scheme for B*57/B*57:01 testing since 2008.

Undisclosed samples, a mixture of random and selected normal healthy subjects' whole blood donations, were dispatched twice a year.

Participants reported on the samples' B*57/B*57:01 status. Laboratories failing to report the 75% consensus findings on one or more samples/year were considered 'unacceptable performers'.

Here we present 4 years of findings for this External Quality Assessment scheme.

Number of participants

Participant numbers increased year on year from 28 in 2008 to 40 in 2011 and, in 2011, included laboratories from 12 countries.

Methods of testing

The methods of choice (September 2011) were:

- ❑PCR-SSP (52.5% of laboratories)
- ❑PCR-SSO and -SSP (20%)
- ❑PCR-SSP and SBT (12.5%)
- ❑PCR-SSO (5%)
- ❑PCR-SSO and SBT (5%)
- ❑Real-time PCR (5%)

Samples

A total of 28 samples [B*57:01 (n=20), B*57:03 (n=1), B*57 negative (n=7)] were distributed over the 4 year period.

Reports

982 reports were returned (734 relating to B*57 positives and 248 to B*57 negatives).

*HLA-B*57:01 samples*

- ❑94.9% (666/702) of the B*57 positive reports on the 20 B*57:01 samples were correct to the 2nd field level
- ❑1 report was incorrect (B*57:11)
- ❑28 reports were at the 1st field level only
- ❑7 were groups of 2 or more alleles containing B*57:01

*HLA-B*57:03 sample*

- ❑83.3% (25/30) of reports on the B*57:03 sample were correct to the 2nd field level
- ❑3 reports were 2-5 allele groups containing B*57:03
- ❑1 laboratory reported "B*57 not B*57:01"
- ❑1 participant reported to the 1st field level only

Overall findings

There were:

Two false B*57 negative reports - in different years and involving different laboratories

No false B*57 positive findings

The overall detection of **B*57 was 100% specific and 99.7% sensitive** while that of **B*57:01 was 100% specific and 95.1% sensitive.**

Comment

Overall these results are clearly "good". However, the findings emphasize the continuing need for this EQA scheme to ensure that laboratories and their users have on-going confidence in their patient B*57:01 assignments.