

An International External Quality Assessment Scheme for Hepatitis C Virus Genotyping.

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Background and Objectives

Genetic testing can exhibit variable results. In 2005 the National Serology Reference Laboratory, Australia (NRL) commenced an external quality assessment scheme (EQAS) for genotyping of Hepatitis C virus (HCV). The broad objectives of the EQAS were to assess whether participants were able to obtain genotyping results that were concordant with those of the reference laboratory and to establish whether the choice of genotyping method influenced the genotyping results obtained. The specific aims of the 2005 EQAS were to establish whether participants were able to identify correctly commonly occurring HCV genotypes and subtypes and identify samples that were duplicated within and between EQAS panels.

Methods

The EQAS was offered as an international programme that provided a challenge format of five samples, three times a year. To address the aims the 2005 HCV Genotyping EQAS, participants were supplied with three identical panels that each contained four different samples (one sample was included in duplicate and samples were identified differently in each panel). All stock samples were assigned a genotype/subtype by nucleic acid sequencing of the HCV *core* gene. Each stock sample was assigned the genotype/subtype of the NCBI reference sequence to which it displayed the greatest homology. All stock samples were diluted in BaseMatrix (Boston BioMedica) to a final concentration of approximately 10,000 IU/mL. All panel members were prepared and dispensed into aliquots at the same time. The samples were stored at -70°C before distribution.

Results

Twenty one laboratories from three countries (Australia, New Zealand and Japan) participated in the HCV Genotyping EQAS in 2005. The participants used commercially-produced and in-house assembled assay systems that targeted the *5'utr*, *core* and *env* genes. Of the 21 participants, 16 (76%) reported results for all three EQAS panels. Of these 16 participants, 14 (88%) reported the correct genotype for each sample in all three EQAS panels. The incorrect results arose from errors in result transcription. One participant demonstrated difficulties in obtaining reproducible results in all three EQAS distributions using a *core/env*-based sequencing technique.

Conclusion

The majority of participants demonstrated an ability to deliver reproducible genotyping results for samples having commonly occurring genotypes. However the EQAS also demonstrated that incorrect genotyping results (that could influence significantly a clinician's decision regarding patient therapy) can arise through simple errors such as inaccurate transcription. The EQAS also highlighted the difficulties that can arise in controlling the quality of assembled assay systems.