The Experience of Determination of Genotypes of Hepatitis C Virus Using Abbott RealTime HCV Genotype II Assay in a Taiwan Medical Center

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Background/Objective
The Abbott RealTime HCV Genotype II (Abbott Molecular Inc.) is an in-vitro diagnostic assay for hepatitis C virus (HCV) genotyping using a real-time polymerase chain reaction (PCR) technology. Determination of HCV genotypes is crucial for its association with clinical response to anti-viral therapy. A prospective evaluation of testing efficiency of this assay was conducted in a CAP-accredited clinical laboratory at the Changhua Christian Hospital.

Method
All clinical specimens submitted for HCV genotyping were tested with Abbott RealTime HCV Genotype II targeting 5' untranslated region (5'UTR) and nonstructural protein 5b (NS5b) of HCV genome for genotyping 1, 2, 3, 4, 5, 6 and Ia, 1b, respectively. The HCV RNA was automatically extracted from plasma on the Abbott m2000sp and real-time PCR was then performed on the Abbott m2000rt. For those specimens with a genotype indeterminate or unsubtypable genotype 1, a manual sequencing analysis targeting 5'UTR after running PCR was carried out to determine HCV genotypes. The results of two methods were evaluated.

Result
A total of 636 clinical specimens were consecutively submitted for HCV genotyping. Of them, 59 (9.3%) specimens fulfilled the criteria for reflexive sequencing analysis. Eighteen indeterminate samples were manually determined as genotypes 1 (n=4), 1b (n=4), 2 (n=6), 6 (n=3) and mixed types of 1b and 6 (n=1). Of 41 samples of unsubtypable genotype 1, one failed in manual genotyping but the others were determined as genotypes 1 (n=14), 1a (n=5), 1b (n=19) and mixed types of 1b and 1c (n=2).

Conclusion
In our experience, the testing efficiency of the Abbott assay was over 90% resulting in a less labor-intensive workload in comparison to manual method. By using reflexive sequencing analysis, the clinically significant genotype 1b could be demonstrated in 27.8% of indeterminate samples and in 51.2% of unsubtypable samples of genotype 1 by Abbott assay.