Post-market Surveillance for the Performance of Anti-HCV *In Vitro* Diagnostic Devices

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ABSTRACT

Hepatitis C virus (HCV) infection is the most common chronic blood-borne viral infection in the world. Most of these patients are chronically infected and might not be aware of their infection because they are not clinically ill. Infected persons serve as a source of transmission to others and are at risk for chronic liver disease or other HCV-related chronic diseases following initial infection. In Taiwan, lots of people were infected by HCV due to the blood reception. The anti-HCV *in vitro* diagnostic devices have been introduced for screening the blood since 1992, and thus reducing the infection of HCV. So the performance of anti-HCV *in vitro* diagnostic devices is extremely important to maintain the safety of blood usage.

Our study surveyed the performance of anti-HCV *in vitro* diagnostic devices which is approved to market by DOH in Taiwan. The study used HCV serum standards to survey these products. The data indicated that most of the products can identify the reference standards and panels except 2 native products. This study will help us improve the blood usage safety and will serve as the reference for further post-market surveillance.

Key words: hepatitis C, in vitro diagnostics, post-market surveillance