

## Abstract

Transfusion is an important therapeutic procedure in modern medicine. Although blood transfusion can save the lives of patients, it also put them at the risk of blood-borne viral infections such as HIV, HBV and HCV. To reduce the risk of blood transfusion, the blood donor screening for HBV, HIV and HCV has been started in 1970s, 1980s and 1990s. Most of the current screening tools are using the EIA to detect the viral antigens or antibodies in the blood of donors. Although these measures have dramatically reduced the chance of post-transfusional viral infection, the residual risk remains because of the existence of "window period" in the donors with early-stage infection. To achieve the goal of zero risk of blood transfusion by shortening the window period, some European countries and the United States attempted to screen the blood donors by using the ultrasensitive PCR techniques (NAT, nucleic acid amplification test) to detect viral genomes. Taiwan is endemic for HBV infection, and 15 to 20% of the general population are HBV carriers. In addition, about 80% of the general population are positive for anti-HBc, indicating a past infection of HBV. Although the Blood Center in Taiwan started to screen blood donors for persistent HBV infection by HBsAg since early 1970s and a good effect has been documented, acute HBV infection in the recipients is not uncommon. We therefore conducted a study to evaluate the feasibility of screening the HBsAg-negative blood donors by using a semiautomatic commercial HBV quantification assay (Cobas Amplicor HBV Monitor). With the help of Blood Services Foundation of the Republic of China, a total of 600 serum samples were collected from HBsAg-negative volunteer blood donors. These samples were divided into 4 groups by the results of HBV markers (anti-HBs and anti-HBc) and then subjected to minipool NAT assays. Our results showed that among the HBsAg-negative blood donors, 61% were positive for anti-HBc, indication a past natural infection of HBV and 25% were negative for both antibodies. The data of minipool NAT assays showed that the current commercial HBV quantification test is not sensitive enough as a screening tool for extremely low level of HBV DNA. In addition, the lack of full automation also undermines this test to serve as a NAT assay for blood donors in Taiwan. Further studies on more sensitive assays as well as fully automatic apparatuses are thus needed to solve this important issue.

**Key Word :** HBV;nucleic acid testing 、HBsAg;donors 、Cobas amplicor system