## **Abstract**

The HBV carrier presents 100-fold increase in risk to develop into HCC. Therefore, it is an important public health issue to early diagnose and treat HBV infection. The HBV surface antigen is an important marker for estimating HBV infection. In the late or nonreplicative stage of HBV infection, a novel type of HBS mutation, the pre-S mutation, has been identified. Such mutations have shown high correlation with HCC progression. This study aims to develop a screening test to predict HCC risk in the chronic HBV carriers.

In this study, we collected sera from the patients that enrolled in the "Hepatitis Protection Health Insurance Program". The HBV surface gene in these sera was analyzed by nested PCR. The PCR products of HBV surface genes were cloned into TA plasmid cloning vectors and fully sequenced. In total, 1428 serum specimens have been investigated. The age and sex distributions are summarized in Table 1. Most of the participants had blood drawn before receiving the treatments with anti-viral drugs lamivudine and interferon. Given that the HBV-related HCC is predominant in males in the ages of 40 to 60 years old, we focused on the analysis of this population. In total, 540 males in the ages of 40 to 60 were analyzed. Among them, the prevalence rate for pre-S mutations is as high as 31% (Table 3), indicating that the pre-S mutation is a common effect in patients with chronic HBV infection.

Keyword: hepatitis B virus, HBsAg, pre-S mutant HBsAg, hepatocellular carcinoma