A case of HCV-positive conversion in antibody testing for hospital staff —From follow-up—

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Abstract

HCV antibody testing is a screening test for the hepatitis C virus (HCV). Numerous immunological measurement methods are presently being used. However, the reactivity of testing reagents may vary depending on the differences in measurement methodology and equipment even when the reagents are made by the same manufacturer. In this paper, we report a case of an individual who tested positive in HCV antibody testing for staff at Hospital A but later tested negative in a reexamination conducted at another institution. This case was referred to the distributor of the testing reagent for closer scrutiny. We also performed a follow-up using a modified reagent with improved reaction specificity. By using the serum sample of this case, we were able to respectively reproduce the same results as obtained at Hospital A and the other institution with reagents with the same lot number. The HCV core antigen levels were below the detectable limit.

The result of an HCV antibody profile test was negative. In a test using different HCV antigen particles, high levels of luminance count compared to those of the HCV antibody–negative control serum were detected in all particles including unsensitized ones. The patient also tested negative with the modified reagent with improved HCV antibody specificity. These results indicate that before the HCV-positive conversion occurred and after the last negative result was obtained, some sort of immunological stimulus might have induced the production of nonspecific substances in the patient's blood that would react to different antigen particles in the reagent. Moreover, these results also indicate that the use of modified reagents with improved specificity might reduce the likelihood of nonspecific reactions. Tottori J. Clin. Res. 8(1), 74-79, 2016

Key Words: Hepatitis C virus (HCV), HCV antibody testing, screening, HCV-RNA testing, antibody profiling, different antigen particles

1. Introduction

Hepatitis C is a hepatic disease caused by HCV infection. In Japan, there are estimated to be between 1.5 and 2 million individuals with persistent HCV infection (HCV carriers). It has recently become known that some HCV carriers can develop liver cirrhosis and liver cancer. The HCV is primarily transmitted via blood, and in the past, many cases of infection were caused by blood transfusion and administration of blood preparations. In 1989, however, blood centers nationwide adopted a testing method aimed at preventing HCV infection, namely HCV c100-3 antibody testing (first-generation antibody testing). Since then, next-generation antibody testing methods with higher accuracy have been introduced one after another, making HCV infection via

blood transfusion a rarity. Moreover, the introduction of HCV-RNA testing in 1999 has further improved the safety of blood transfusion and preparations.

HCV antibody testing is the method of choice for screening HCV infection. However, as there are many immunological measurement techniques, levels of reactivity may vary depending on the differences in measurement methodology and equipment even when reagents made by the same manufacturer are used. Normally, individuals with HCV antibody–positive serum are divided into "HCV carriers" and "already infected patients". For clearer differentiation, the most common modality presently employed is to perform either HCV core antigen testing or nucleic acid amplification testing (NAT) on HCV antibody–positive