Comparision of Diagnostic Efficacy of Rapid Diagnostic Assays Used for the Detection of Hepatitis B Virus Surface Antigen

E.W.S. Chameera[1,2], F. Noordeen[1], H. Pandithasundara[1] and S.B. Abeykoon[1]

[1]Department of Microbiology, Faculty of Medicine, University of Peradeniya
[2]Department of Medical Laboratory Science, Faculty of Allied Health Sciences, University of Peradeniya

There are different tests available for the detection of hepatitis B surface antigen (HBsAg), which is the main viral marker in hepatitis B diagnosis. Enzyme immuno asaays (EIA) and polymerase chain reaction (PCR) are the most sensitive methods in detecting HBsAg. However, rapid tests are intended for qualitative detection of HBsAg in human serum, plasma or whole blood wherever EIA methods are impractical or cannot be sustained. Several rapid diagnostic tests were developed for screening HBsAg and the majority are based on immuno-chromatographic principle. Immunochromatographic assays (ICA) are cheaper, faster and are easy to perform when compared with EIA, but reliability of these assays varies. The reliability of the test is very important because HBV infection is a serious and silent infection in some patients. The current study was planned to compare two rapid diagnostic test kits, CORTEZ'S HBsAg one step detection kit (Cortez Diagnostics Inc, USA.) and CTK Biotech's Onsite HBsAg rapid test (CTK Biotech Inc, USA) in detecting HBsAg in serum using the SURASE B-96 (TMB) enzyme immunoassay (General Biologicals Corp, Taiwan) as the gold standard method.

Fifty blood samples received by the Department of Microbiology, Faculty of Medicine, University of Peradeniya for detecting HBsAg between April and August 2010 were tested using the above two tests. Moreover, the SURASE B-96 (TMB) EIA was also performed on these samples.

The gold standard SURASE B-96 ELISA detected 45 samples as HBsAg negative and 5 samples as HBsAg positive.Four samples were HBsAg positive with CTK Biotech's Onsite HBsAg rapid test and 46 samples were HBsAg negative. Hence, the specificity and positive predictive value (PPV) were 100% but sensitivity and negative predictive value (NPV) were 80% and 97.82%, respectively. CORTEZ'S HBsAg one step detection kit detected 3 samples as HBsAg positive and 47 samples as HBsAg negative, giving specificity and PPV as 100% and sensitivity and NPV as 60% and 95.74%, respectively.

Both ICAs showed less sensitivity and NPV than the EIA. Sensitivity and NPV were higher in Onsite HBsAg kit than the CORTEZ'S HBsAg kit making the former slightly better than the latter for detecting serum HBsAg. Many studies have noted that the specificity and the PPV of the ICAs to be high but sensitivity and the NPV to be low as observed in our study. In conclusion, the accuracy of ICA can vary when compared to EIA. Hence, assessing and validating ICA at regular intervals routinely and/or when changing to a new ICA, will give an idea on the accuracy rate of the ICA used by a particular laboratory in countries where ICA are commonly used.