

P0804 Performance evaluation of the EuDx-HE (A,B,C) kit for Point-of-Care testing of hepatitis A, B, and C viruses in patients with viral hepatitisMi-Kyung Lee*¹, Oh Joo Kweon¹, Yong Kwan Lim¹, Hye-Ryoun Kim¹, Tae-Hyoung Kim²¹ Department of Laboratory Medicine, Chung-Ang University College of Medicine, ² Department of Urology, Chung-Ang University College of Medicine

Background: Hepatitis A, B, and C viruses (HAV, HBV, and HCV, respectively) are the most common pathogens that have been etiologically associated with viral hepatitis. Although enzyme immunoassay plays a major role to detect these viruses in hospital setting, the needs for point-of-care testing which allows rapid and simultaneous detection of the viruses are increasing. We evaluated EuDxTM-HE(A,B,C) KIT (EUDIPIA Inc., Cheongju, Republic of Korea), which detect anti-HAV IgM, HBsAg, and anti-HCV simultaneously using a immunochromatographic method within 15 minutes.

Materials/methods: We analyzed 57 anti-HAV IgM-positive, 477 HBsAg-positive, and 451 anti-HCV-positive samples and 596 triple-negative samples with EuDxTM-HE(A,B,C) KIT. We investigated the diagnostic accuracy including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) comparing to the results of Abbott Architect[®] anti-HAV IgM, HBsAg, and anti-HCV immunoassays (Abbott, Chicago, IL, USA). To compare the analytical performance with other point-of-care testing, the samples were tested at the same time with "SD Bioline HAV IgM/IgG (Abbott)", "SD Bioline HBsAg (Abbott)", and "SD Bioline HCV (Abbott)".

Results: For anti-HAV IgM, the sensitivity, specificity, PPV, and NPV of EuDxTM-HE(A,B,C) KIT and SD Bioline HAV IgM/IgG were 94.74%/89.47% (EuDxTM/SD Bioline), 99.41%/99.61%, 85.71%/89.47% and 99.80%/99.61%, respectively. For HBsAg detection, the values of EuDxTM-HE(A,B,C) KIT and SD Bioline HBsAg were 98.53%/94.13%, 99.09%/99.28%, 97.92%/98.25%, and 99.36%/97.51%, respectively. Finally, the sensitivity, specificity, PPV, and NPV for detecting anti-HCV by EuDxTM-HE(A,B,C) KIT and SD Bioline HCV were 96.45%/91.57%, 99.56%/99.03%, 98.86%/97.41%, and 98.6%/96.72%, respectively. Positive and negative concordance rates between EuDxTM and SD Bioline was 89.47% and 99.21% with kappa of 0.84 for anti-HAV IgM, 98.25% and 97.24% with kappa of 0.94 for HBsAg, and 97.64% and 97.75% with kappa of 0.94 for anti-HCV, respectively.

Conclusions: We concluded that the EuDxTM-HE(A,B,C) KIT have acceptable clinical performance in detecting anti-HAV IgM, HBsAg, and anti-HCV. Therefore, it can be reliable and useful point-of-care testing which allows rapid and simultaneous detection of the HAV, HBV, and HCV.

