Qualification assessment of commercially available anti-HDV ELISA kit in comparison to in-house developed, ultra-sensitive, fluorescence immunostaining slide assay

Odgerel Oidovsambuu[1,2,3], Bekhbold Dashtseren[1,2,4], Purevsuren Bat-Ulzii[1,2], Bujin Lkhamsuren[5], Enkhriimaa Bat-Erdene[5], Tsend-Ayush Batbold[5], Xiaohua Chen[6], Ping Liu[6], Dahgwhadorj Yagaanbuyant[3], Naranjargal Dashdorj[2], Jeffrey Glenn[6], Naranbaatar Dashdorj[2]

[1]Liver Center, [2] Onom foundation, [3]National University of Mongolia, [4]National University of Medical Sciences, [5]New Mongol Technological Institute, [6]Stanford University

Introduction

Quality issues of diagnostic kits are always in the center of attention of biomedical field. There are relatively few numbers of HDV-testing ELISA kits, which are dominantly used in the world. Qualification assessment of those kits by comparing to other ELISA kits or other detection assays including fluorescence immunostaining, chemoluminescence immunoassay are not well demonstrated. In this study, we did qualification assessment of Diasorin anti-HDV ELISA kit by comparing it to ultra-sensitive, fluorescence immunostaining slide assay (FISA), which is developed at Stanford.

Methods

Total of 123 HBsAg positive samples were used for detection of anti-HDV (total antibody) by Diasorin ELISA kit and FISA. Also all of samples were tested for HDV-RNA by QPCR.

Results

Out of 123, there were 6 samples that were identified to be anti-HDV negative by ELISA, while anti-HDV positive by FISA. 3 of those 6 samples were identified as positive for HDV-RNA. In other words, Diasorin ELISA kit had 3 false negatives. Additionally, 9 samples were identified to be anti-HDV positive by Diasorin ELISA kits, were identified to be false positives by FISA. These samples were confirmed to be, indeed, false positives by QPCR HDV-RNA.

Conclusion

This result indicates that our in- house developed FISA assay is superior in both sensitivity and specificity in comparison to commercial ELISA kits, and consequently more confident with QPCR results for HDV-RNA detection. Also, our results suggest that current diagnosis for HDV detection using ELISA kits may produce false negative results, thus possibly underestimating HDV prevalence in some regions of the world.