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Development of a Highly Sensitive ELISA for Quantification of Hepatitis B Virus (HBV) Surface Antigen (HBsAg)

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Abstract: Background: Hepatitis B Virus (HBV) infection is of global importance and many studies are aimed to develop more sensitive diagnostic tools and improve therapeutic options. HBV infection is diagnosed and followed-up basically by serological studies, among which the enzyme-linked immunosorbent assay (ELISA) is widely used. Aim: To develop a sensitive HBsAg ELISA for both research and diagnostic purposes. Materials and Methods: A hybridoma (clone 4D1) secreting anti-HBs IgG2a monoclonal antibody (mAb) was used for the establishment of our in-house ELISA. Tests were performed for both cell culture medium and human sera. The hepatoma cell lines of human origin PLC/PRF/5 and Hep G2 were used for validation assays. Tests for human sera were run concurrently with the Access® Immunoassay System. Results: The in-house ELISA system had an analytical sensitivity less than 0.41 ng/ml for both human sera and cell culture medium. The performance comparison of our in-house ELISA system with the Access® Immunoassay System even for samples with s/co levels of 1.5-13.7 gave a significant correlation. Conclusions: These reliable results of the newly established HBsAg ELISA system make it a promising candidate for diagnostic as well as research purposes.

Key Words: HBsAg, monoclonal antibody, ELISA

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