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Performance evaluation of BIO-FLASH HBeAg and BIO-FLASH anti-HBe on Biokit's BIO-FLASH analyser

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Background: Hepatitis B infection is a liver infection caused by the Hepatitis B Virus (HBV) that represents a major health concern. One of the many serological markers that appear during the viral infection of HBV is the Hepatitis B e antigen (HBeAg). This antigen is detectable as a soluble protein in serum, as it is secreted from infected liver cells, and is found in the early phase of hepatitis B infection or in chronic infection if there is viral replication. During recovery from acute Hepatitis B, after HBeAg levels decline and become undetectable, anti-HBe antibodies appear in serum. BIO-FLASH HBeAg is a chemiluminescent, two-step immunoassay designed for the qualitative detection of Hepatitis B e antigen in human serum and plasma. BIO-FLASH anti-HBe is a chemiluminescent, inhibitory two-step immunoassay designed for the qualitative detection of antibodies against HBeAg in human serum and plasma. The aim of this study was to evaluate the performance of the two assays on the BIO-FLASH® analyser.

Material/methods: A method comparison was performed by comparing the new BIO-FLASH assays to the ARCHITECT HBeAg and anti-HBe (Abbott Laboratories) with two subsets of serum samples from the laboratory HBV routine (249 for HBeAg and 232 for anti-HBe, tested at different dates). Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were calculated according to CLSI EP12-A2. Discordant samples were further analysed with other commercially available assays. Precision of the BIO-FLASH assays was also assessed following a CLSI EP15-A3 design.

Results: For BIO-FLASH HBeAg, PPA and NPA were 96.2% (50/52) and 100.0% (197/197) respectively. From the two presumable BIO-FLASH false negative samples, one was classified as acute late HBV, showing seroconversion from HBeAg to anti-HBe, the other classified as chronic HBV with a very low positive HBeAg value for ARCHITECT. Additionally, when analysed with VIDAS HBe assay (Biomerieux), the two samples results agreed with BIO-FLASH. Total precision was 0.032 SD for the Negative Control (0.34 S/CO) and 4.7% CV for the Positive Control (3.16 S/CO). For BIO-FLASH anti-HBe, PPA and NPA were 98.1% (51/52) and 100.0% (178/178) respectively. Two samples were equivocal and were taken out of calculations. The remaining presumable BIO-FLASH false negative sample was tested with VIDAS anti-HBe (Biomerieux) and with Cobas anti-HBe (Roche Diagnostics) assays, results agreeing in both cases with BIO-FLASH. Total precision was 1.7% CV for the Negative Control (3.02 S/CO) and 5.0% CV for the Positive Control (5.00 S/CO).

Conclusions: In terms of agreement to commercially available methods and precision, the BIO-FLASH HBeAg and BIO-FLASH anti-HBe assays show excellent performance, which together with the features of the BIO-FLASH® analyser (random access, easy-to use, and full automation), make them a perfect choice for routine use in a clinical laboratory.