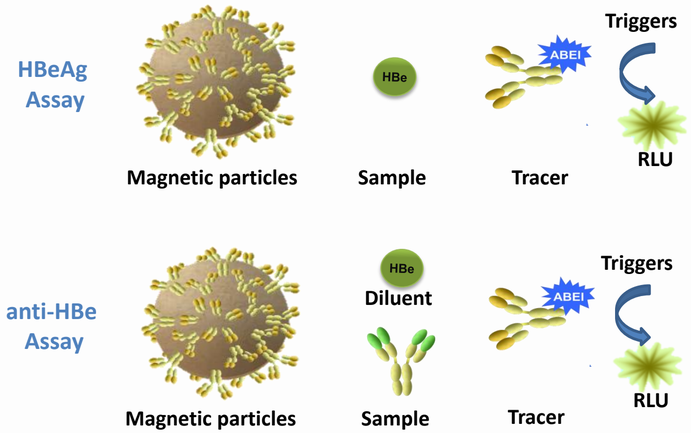
Performance Evaluation of BIO-FLASH® HBeAg and BIO-FLASH® anti-HBe on Biokit's BIO-FLASH® Analyser

E. CAMACHO[1], M. MARTOS[1], S. FARAUDO[1], C. MUÑOZ[2], P. BERENGUER[2], D. GILES[1] . [1]Biokit Research & Development, Barcelona, Spain and [2]Hospital de la Santa Creu i Sant Pau, Barcelona, Spain

INTRODUCTION AND PURPOSE

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. Serum levels rise rapidly during the period of viral replication. During recovery from acute Hepatitis B, after HBeAg levels decline and become undetectable, HBe antibodies (anti-HBe) appear in circulation.

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.



The aim of this study was to evaluate the performance of the new assays when testing samples from HBV routine diagnosis in comparison with the commercial assay in use in the Department of Microbiology at the Hospital de la Santa Creu i Sant Pau (Barcelona, Spain).

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 unselected serum samples from the laboratory HBV routine (249 for HBeAg and 232 for anti-HBe, tested at different dates).

481 HBV routine samples

- 14.2% pregnant women
- 13.3% HIV patients follow up
- 9.8% onco-hematologic diseases
- 7.4% sterility studies
- 55.3% other diagnostics

Table 1: Patients characteristics

Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were calculated according to CLSI EP12-A2 Guideline. Discordant samples were further analyzed with other commercially available assays. Precision of the BIO-FLASH® assays was also assessed following a 5 days x 1 run x 5 replicates design as per CLSI EP15-A3.

RESULTS

Of the 249 samples analysed for HBeAg, 52 corresponded to reactive results (positive) and 197 non-reactive (negative) results by ARCHITECT HBeAg. 247 of 249 samples tested showed concordant results when analysed with BIO-FLASH® HBeAg.

	ARCHITECT HBeAg	
BIO-FLASH HBeAg	POS	NEG
POS	50	0
NEG	2	197

BIO-FLASH vs. ARCHITECT HBeAg	
PPA (95% CI)	96.2% (87.0-98.9)
NPA (95%CI)	100.0% (98.1-100.0)
Overall Agreement % (%)	99.2% (97.1-99.8)

Table 2: Comparative results for the HBeAg assay

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 results, 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 the VIDAS HBe/anti-HBe assay (bioMérieux), the two samples results agreed with BIO-FLASH® results.

	ARCHITECT Anti-HBe		
BIO-FLASH anti-HBe	POS	IND	NEG
POS	51	0	0
IND	2	0	0
NEG	1	0	178

BIO-FLASH vs. ARCHITECT anti-HBe	
PPA (95% CI)	98.1% (89.9 - 99.7)
NPA (95%CI)	100.0% (97.9 - 100)
Overall Agreement % (95%CI)	99.6% (97.6 - 99.9)

Table 3: Comparative results for the anti-HBe assay

For BIO-FLASH® anti-HBe, a total of 232 samples were analyzed, corresponding to 54 reactive results and 178 non-reactive results by ARCHITECT anti-HBe. Two samples were considered Indeterminate as resulted in values within the grey zone for BIO-FLASH® anti-HBe (> 0.80 - ≤ 1.20 S/CO). 229 of 232 (98.7%) showed concordant results between ARCHITECT anti-HBe and BIO-FLASH® anti-HBe. PPA and NPA were 98.1% (51/52) and 100.0% (178/178) respectively. The presumable BIO-FLASH® false negative result was tested with the VIDAS HBe/anti-HBe assay (Biomerieux) and with Cobas anti-HBe (Roche Diagnostics), and in both the same result than in BIO-FLASH® was obtained. All discordant samples showed a low positive value for ARCHITECT.

BIO-FLASH® HBeAg and BIO-FLASH® anti-HBe assays showed good precision (total coefficient of variation percentage, CV%) when using the corresponding negative and positive controls .

Precision (Total CV%)	BIO-FLASH HBeAg		BIO-FLASH anti-HBe	
	Target Value	Result	Target Value	Result
Negative Control	0.30 S/CO	0.032 SD	3.00 S/CO	1.7 %CV
Positive Control	3.00 S/CO	4.7 %CV	0.50 S/CO	5.0 %CV

Table 4: Precision Results for BIO-FLASH HBeAg and anti-HBe assays

CONCLUSIONS

In terms of agreement to commercially available methods and precision, the two assays show suitable performance. Taken together with the features of the BIO-FLASH® analyser (random access, easy-to use, and full automation), the BIO-FLASH® HBeAg and BIO-FLASH® anti-HBe assays are an excellent choice for routine use in a clinical laboratory.

Biokit
A Werfen Company

HOSPITAL DE LA SANTA CREU I SANT PAU
UNIVERSITAT AUTÒNOMA DE BARCELONA