EVALUATION OF THE DETERMINE™ HBsAG RAPID TEST AS A POINT-OF-CARE SCREENING TOOL FOR THE DIAGNOSIS OF HEPATITIS B VIRUS INFECTION

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Introduction

Importance of Hepatitis B

• Hepatitis B Virus (HBV) is a major global health problem causing substantial morbidity and mortality.
• 240 million people are chronically infected with this virus despite the availability of a vaccine for more than 2 decades.
• SubSaharan Africa has a >8% prevalence of HBsAg.

Importance of screening

•Screening pregnant women, the partners and household contacts of those with active infection and other high risk groups using a point-of-care test (POCT) would be an effective public health response to this important infection.
• With the increasing availability of effective anti-HBV therapies like tenofovir, identifying those who have active infection is a priority.
The rollout of HIV rapid testing in resource poor settings using a POCT is the basis of the HIV response and is proof of concept for a similar response to HBV.

Aim

To compare the performance characteristics of the Determine™ HBsAg Rapid test with the automated AxSYM® HBsAg assay (Abbott Laboratories, Abbott Park, IL USA) and the manual Murex HBsAg Version 3 (DiaSorin S.p.A, Saluggia, Italy) assay.

Methods

The study was conducted in the Division of Medical Virology at Stellenbosch University, Cape-Town.

A total of 151 samples which were in storage in the Division and which had previously been screened for HBsAg with the AxSYM® HBsAg assay were tested using the Murex HBsAg Version 3 in parallel with the Determine™ Rapid strip. The rapid strip was kept at room temperature for the duration of the study.

Test performance was based on sensitivity (Se), specificity (Sp) and positive and negative predictive values (PPV, NPV).

Serial dilutions were used to show the limit of detection (LOD) using the WHO NIBSC HBsAg Standard. Interference testing was performed.

Acknowledgements

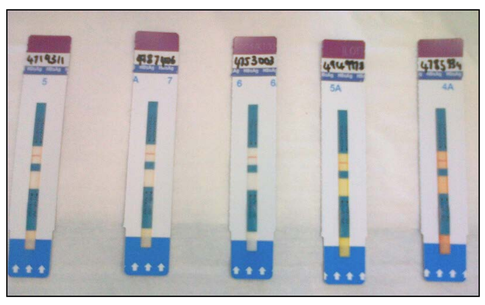
We would like to thank Dr Dieter Glebe, Gilead and Alere™.

Results

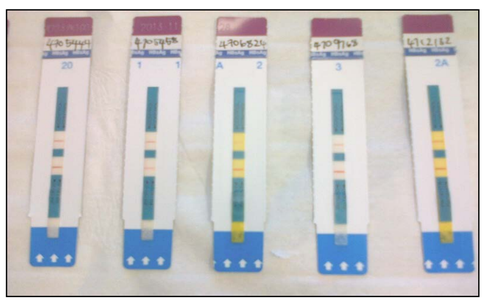
Distribution of samples

HBsAg High Positive	HBsAg Low Positive	HBsAg Negative	Total
91	4	56	151

Determine™ HBsAg Rapid Test



Negative



Positive

Diagnostic accuracy

		True HBsAg Status		
		+	-	
Results of Determine™ Rapid test strip	+	92	0	92
	-	3	56	59
		95	56	151

• The 3 false negative samples had very low HBsAg titres, likely to be from patients who are clearing infection.

• The LOD of the rapid assay was 3.20 IU/ml. Laboratory ELISA's have a LOD of at least 0.5 IU/ml.

Determine™ HBsAg	%	95% CI
Sensitivity	96.8	94 – 99.6
Specificity	100	
PPV	100	
NPV	94.92	91.42 – 98.42

Interference testing

Interferent	Interferent level	Pool 1	Pool 2
βHCG	21874 IU/L	NSI	NSI
Bilirubin	259.3 µmol/L	NSI	NSI
Haemolysis (Hb)	4+ (10.6 g/dL	NSI	NSI
Lipaemia (High TG)	51.2 mmol/l	NSI	NSI
Rheumatoid Factor	557IU/mL	NSI	NSI

NSI = No significant interference

Discussion

In this evaluation we found that the Determine™ HBsAg rapid assay has acceptable performance characteristics that make it suitable for roll-out as a POCT to identify active HBV infection. The ease of use, stability at room temperature, small sample volume (50 µl) and short turn-around-time (15 minutes) are additional favourable characteristics. The lower sensitivity of HBsAg detection is not clinically significant in our setting.

Conclusion

We have evaluated the Determine™ HBsAg rapid assay and have shown it to have acceptable performance in our setting. Studies using this assay as a POCT in the clinic are now urgently needed.