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Evaluation of the Performance of the First Response HBsAg Rapid Test

Background

UVRI was requested by the Ministry of Health to evaluate the performance of the First Response Hepatitis B Surface Antigen (HBsAg) Rapid Test against a panel of well-characterized specimens for which the HBsAg results were known. Accordingly, 221 positive and 172 negative HBsAg anonymous plasma specimens were identified from UVRI specimen repositories and tested on the First Response HBsAg RT.

Gold-standard Reference Method

The testing algorithm for the reference specimens was as follows;

All specimens were first tested for HBsAg on the Abbott Murex HBsAg EIA, v3 following the manufacturer's protocol. Specimens positive on the HBsAg EIA were further tested on the Murex HBsAg Confirmatory EIA, v3 again following the manufacturer's protocol with additional testing using the COBAS[®] AmpliPrep/COBAS[®] TaqMan[®] HBV Test, v2.0 for specimens that could not be resolved after dilution.

Comparison of Results for First Response HBsAg RT against the Gold-Standard Reference Method

	Gold Standard Reference Method		Total
	Positive	Negative	
First Response HBsAg RT			
Positive	219	0	219
Negative	2	172	174

First Response HBsAg RT Evaluation 1

Total	221	172	393

Summary

393 specimens were tested using the First Response HBsAg RT.

221 were HBsAg-positive specimens and 172 were HBsAg-negative specimens according to the gold-standard reference method.

219 of the 221 HBsAg-gold-standard positive specimens were positive by the First Response HBsAg RT.

2 of the 221 HBsAg-gold-standard positive specimens were negative by the First Response HBsAg RT.

All 172 HBsAg-gold-standard negative specimens were negative by the First Response HBsAg RT.

Conclusion

The performance of the First Response HBsAg RT against the gold standard was as follows;

Sensitivity: $219/221 = 99.1\%$

Specificity: $172/172 = 100\%$

PPV: $219/219 = 100\%$

NPV: $172/174 = 98.9\%$

Kappa: 0.99

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Signed



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Director