HOSPITAL SUNGAI BULOH
SELANGOR

Performance of AHP Rapid HBsAg Test

Intended use

The AHP HBsAg Test cassette is a rapid lateral flow immunochromatographic assay designed for qualitative determination of hepatitis B surface antigen (HBsAg) in Whole Blood, Serum or Plasma. It is intended to be used by professional as a screening test and as an aid in the diagnosis of hepatitis B virus infection. Any reactive specimen with Rapid HBAg Test must be confirmed with alternative testing method(s) and clinical findings.

Manufacturer

Allen Helathcare Products (M) Sdn Bhd. No. 17 Lrg Nagasari 2, Tmn NAgasari, 13600, Perai, Penang, Malaysia.

Test Principle

The AHP Rapid HBsAg Test Device (Whole Blood/Serum/Plasma) is a qualitative immunoassay for the detection of HBsAg in whole blood, serum or plasma. The membrane is pre-coated with anti-HBAg antibodies on the test line region of the Device. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with anti-HBAg antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Test Kit

Lot Number	:	HBA24057733WWB
Expiry Date	:	1/11/2025
Date of Test	:	23/8/2024

Instrument Used

Manually performed

Reagent and Sample Preparation, Result Interpretation
Refer to product package insert in the attachment

Sample Used

Sample Type	=	Serum
Known Positive Sample	=	10
Known Negative Sample	=	10
Total samples used for analysis	=	20

Performance Analysis

		Intended Results		
		Positive	Negative	Total
AHP RAPID HBSAG TEST	Positive	10	0	10
	Negative	0	10	10
	Total	10	10	20

Estimated sensitivity	100%
Estimated specificity	100%
Positive Predictive Value (PPV)	100%
Negative Predictive Value (NPV)	100%
Total Accuracy	100%
Imprecision, Coefficient of unalikeability (%CU)	0%

Conclusion

All samples used for this kit evaluation were previously tested using the chemiluminescence immunoassay (CLIA) method. The estimated sensitivity and specificity results as per manufacturer's claims. The imprecision, calculated as % CU, is less than 10%. The kit is acceptable for use in point-of-care testing (POCT).

Prepared by	Reviewed by
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Disclaimer:

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HOSPITAL SUNGAI BULOH
SELANGOR

Performance of AHP Rapid HCV Test

Intended use

The AHP Rapid HCV Test cassette is a rapid lateral flow immunochromatographic assay designed for qualitative detection of antibodies to hepatitis C virus (HCV) in Whole Blood, Serum or Plasma. It is a qualitative immunoassay and considered as an initial screening test for detection of HCV antibodies. Any reactive specimen with the Rapid HCV Test must be confirmed with alternative testing method(s) and clinical findings. The test is for a professional use only.

Manufacturer

Allen Helathcare Products (M) Sdn Bhd. No. 17 Lrg Nagasari 2, Tmn NAgasari, 13600, Perai, Penang, Malaysia.

Test Principle

Rapid HCV Test is a chromatographic immunoassay (CIA) for the detection of antibodies to HCV in human serum/ plasma or whole blood. The Rapid HCV Test employs a unique recombinant binding protein which is conjugated to colloidal gold dye particles and antigen which are bound to the solid phase membrane. The venous or capillary (fingerstick) whole blood, serum or plasma is applied to the Sample window of test device. Buffer solution is provided in a buffer bottle. The Buffer facilitates the lateral flow of the specimen and test reagents and promotes the binding of the antibodies to the antigen. The specimen/buffer mixture migrates along the test strip by capillary action, reconstituting the conjugate. If present, the antibodies bind to the colloidal gold conjugated antibody binding protein. In a reactive sample, the dye conjugated-immune complex migrates on the nitrocellulose membrane and is captured by the antigens immobilized in the TEST (T) area producing a pink/purple line. In the absence of HCV antibodies, there is no pink/purple line in the TEST (T) area. The sample continues to migrate along the membrane and produces a pink/purple line in the CONTROL (C) area containing goat anti-mouse immunoglobulin G. This procedural control serves to demonstrate that specimen and reagents have been properly applied and have migrated through the device.

Test Kit

Lot Number	:	HCV24077927AWB
Expiry Date	:	01/01/2026
Date of Test	:	23/8/2024

Instrument Used

Manually performed

Reagent and Sample Preparation, Result Interpretation
Refer to product package insert in the attachment

Sample Used

Sample Type	=	Serum
Known Positive Sample	=	10
Known Negative Sample	=	10
Total samples used for analysis	=	20

Performance Analysis

		Intended Result		
		Positive	Negative	Total
AHP RAPID HCV TEST	Positive	9	0	9
	Negative	1	10	11
	Total	10	10	20

Estimated sensitivity	90%
Estimated specificity	100%
Positive Predictive Value (PPV)	100%
Negative Predictive Value (NPV)	91%
Total Accuracy	95%
Imprecision, Coefficient of unalikeability (%CU)	8%

Conclusion

All samples used for this kit evaluation were previously tested using the chemiluminescence immunoassay (CLIA) method. The estimated sensitivity result is below the manufacturer's claims; however, it is still acceptable. The estimated specificity result aligns with the manufacturer's claim. The imprecision, calculated as % CU, is less than 10%. The kit is acceptable for use in point-of-care testing (POCT).

Prepared by	Reviewed by
1/10/24.	
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REFERENCE NO: ITES/2024/0089/E

NATIONAL PUBLIC HEALTH LABORATORY (NPHL)
MINISTRY OF HEALTH MALAYSIA
EVALUATION TEST REPORT OF SYPHILLIS RAPID TEST

Product Name: AHP Rapid Syphilis (TP) Test

Kit/ Assay Intended Used

In-Vitro Diagnostic.

Manufacturer

Allen Healthcare Products (M) Sdn. Bhd.

Test Principle

The principle used in this kit The AHP Rapid Syphilis (TP) test is a qualitative test for the detection of antibodies to T. pallidum in human serum/plasma or whole blood. The Rapid Syphilis Kit is a chromatographic immunoassay (CIA) for the detection of all antibodies, including IgM, IgG and IgA to T. pallidum in human serum, plasma or whole blood. T. pallidum specific antigens are precoated onto membrane as a capture reagent on the test region. During the test, specimen is allowed to react with the colloidal gold particles, which have been labeled with T. pallidum specific antigens, as well. Antibodies to T. pallidum, if present, a red colored band will develop on the membrane. Absence of this red colored band in the test region suggests a negative result. To serve as a procedural control, a red colored band in the control region will always appear regardless the presence of antibodies to T. pallidum. The results are observed in 10 to 20 minutes.

Test Kit/ Assay Information

Batch mp./Identifier:	TPV02CSWB	Lot Number:	TP24037533LWB
Manufacturing Date:	2024-02-05	Expiry Date:	2024-09-01

Instrument Used

Timer

Reagent and sample Preparation

Kindly refer to product package insert in the attachment

Test/ Assay Used:

Sample Type = Whole Blood

Performance Analysis

AHP Rapid Syphilis (TP) Test - Syphilis RTK	Known Sample (NPHL)		Total
	Positive	Negative	
Positive	50	0	50
Negative	0	50	50
Total	50	50	100

Positive Predictive Value:100.00 %
Negative Predictive Value: 100.00 %

Comments

During the kit evaluation, we observed these findings: 1. The single-use buffer provided in this kit is placed in a plastic dropper which looks exactly like the plastic dropper used for collecting blood, serum or plasma samples. The buffer was not labelled to distinguish this difference. 2. The single-use buffer provided in this kit is placed in a plastic dropper with a sealed end and required the use of a scissors to cut of the end before dispensing the buffer solution. Possibility of reagent contamination may occur when users reuse the same scissors to cut off the ends of this buffer droppers without proper decontamination between each kit used.

Prepared by	Reviewed/ Approved By
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HANNAH PHOON YIK PHING	R.PUSPARANI A/P RAMASAMY
Evaluator/ Officer in Charge	Head of Bacteriology Section/ Unit, NPHL

Date: 2024-05-24