THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR KAS HEPATITIS B (HBsAg) RAPID TEST (HEPATITIS B SURFACE ANTIGEN (HBsAg) TEST KIT)

Version number 2.0, 18.05.2026

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1. Introduction

KAS Hepatitis B (HBsAg) Rapid Test is a class D in-vitro diagnostic device belonging to the Clinical Laboratory, Molecular (Virology) specialty category. It is approved in Tanzania as a single use rapid diagnostic test kit for use in adults, children and elderly by healthcare professionals.

1.1. Administrative Information

Registration number	TAN 23 MDR 0228
Brand Name (if relevant)	KAS Hepatitis B (HBsAg) Rapid Test
Common name	Hepatitis B Surface Antigen (HBsAg) test kit
Class of the device and rule applied	Class D as per Rule 1 for classification of In Vitro Diagnostic Devices
GMDN code and term	48322, Hepatitis B virus surface antigen IVD, kit, rapid ICT, clinical
Name and complete address of the Market Authorization Holder	Kas Biotech Limited, Gf 09, Plot No. 11, Umoja Complex, Vingunguti, Area Along Nyerere Road, P.O BOX 7856, Dar Es Salaam, Tanzania
Name and address of local responsible person (LRP).	Kas Biotech Limited, Gf 09, Plot No. 11, Umoja Complex, Vingunguti, Area Along Nyerere Road, P.O BOX 7856, Dar Es Salaam, Tanzania

1.2. Assessment Procedure

The application for registration of KAS Hepatitis B (HBsAg) Rapid Test was submitted on 12/07/2022. The product underwent full assessment. Assessment was completed in two rounds of evaluation. KAS Hepatitis B (HBsAg) Rapid Test was registered on 31/10/2023.

2. Technical information

2.1. Intended use

The intended use of KAS Hepatitis B (HBsAg) Rapid Test as declared by the manufacturer and approved by TMDA is; it is a lateral flow chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) in human whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Hepatitis B virus (HBV). Any reactive specimen with the HBsAg Rapid Test Strip must be confirmed with alternative testing method(s) and clinical findings. KAS

Hepatitis B (HBsAg) Rapid Test is approved for use in healthcare settings by trained professionals only.

2.2. Device details and features

KAS Hepatitis B (HBsAg) Rapid Test is a single device. KAS Hepatitis B (HBsAg) Rapid Test has been registered as a kit which consists of 25 test cassettes, 25 dropper, desiccant and package insert.

KAS Hepatitis B (HBsAg) Rapid Test is a rapid diagnostic device. It is used for screening test and as an aid in the diagnosis of infection with Hepatitis B virus (HBV). Any reactive specimen with the HBsAg Rapid Test Strip must be confirmed with alternative testing method(s) and clinical findings.

KAS Hepatitis B (HBsAg) Rapid Test operates by the principle of the double antibody-sandwich technique. During testing, a Serum/Plasma specimen migrates upward by capillary action. The HBsAg if present in the specimen will bind to the labeled HBsAb antibody-dye conjugate. The immune complex is then captured on the membrane by the pre-coated HBsAb, and a visible colored line will show up in the test line region indicating a positive result. In the absence of HBsAg, a colored line will not form in the test line region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred. The HBsAg Test Strip (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAg in whole blood, serum or plasma specimens. The test utilizes a combination of double monoclonal antibodies to selectively detect elevated levels of HBsAg in whole blood, serum or plasma. The test out-put is qualitative results.

The type of specimen used is whole blood, serum or plasma and is collected by vein puncture following standard laboratory procedures.

Device description

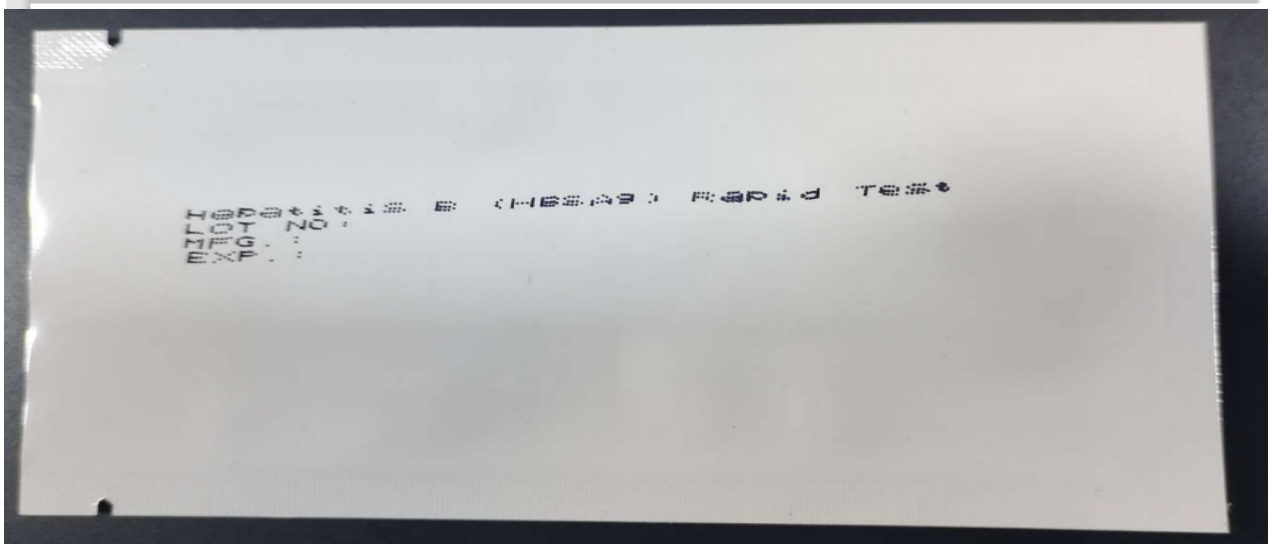
According to the claim of assay description from manufacturer;

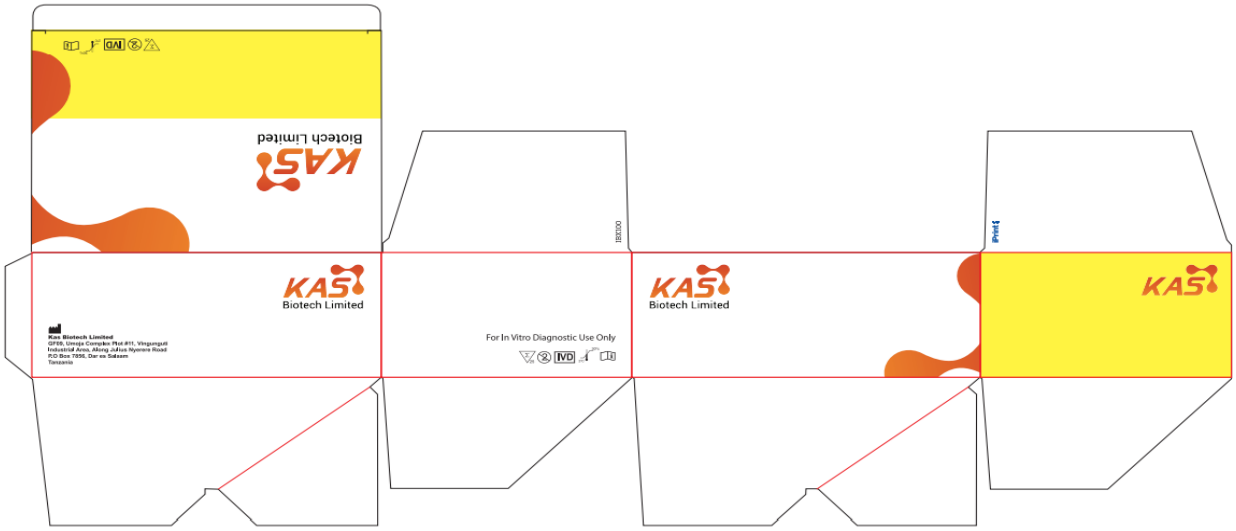
a) **Composition**: The test cassette contains a membrane strip coated with anti-HBsAg antibody (HBsAb) on the test line, goat-anti-mouse IgG on the control line, and a dye pad which contains colloidal gold coupled with HBsAb. The quantity of tests was printed on the labeling.

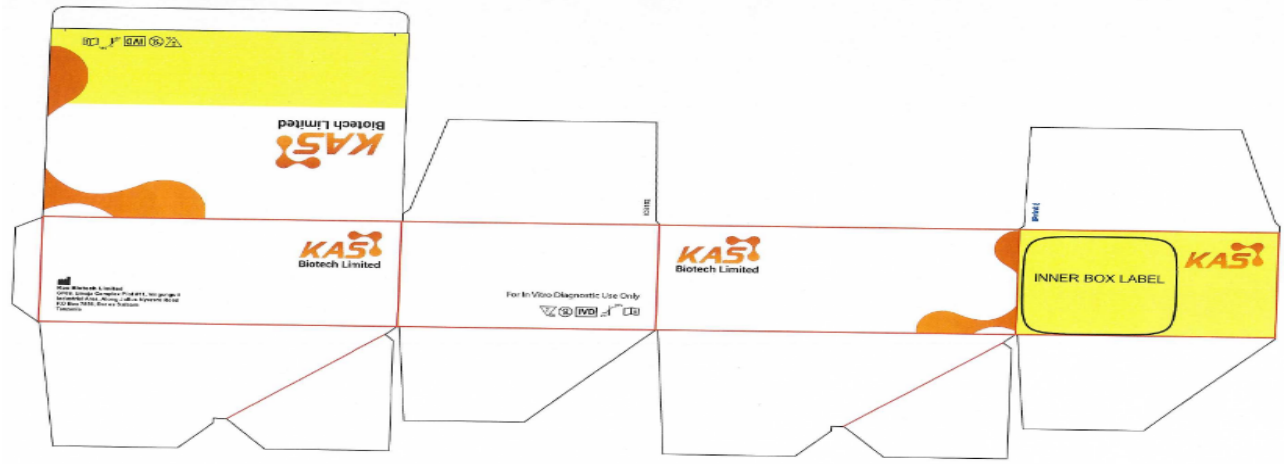
b) **Storage and Stability:**

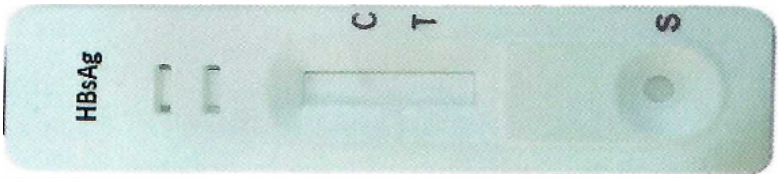
- Store as packaged in the sealed pouch at temperature (4-30℃ or 40- 86℉).
- The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour.
- Prolonged exposure to hot and humid environment will cause product deterioration.

- The LOT and the expiration date were printed on the labeling.









HBsAg. Rapid Test
(25 Tests)

Specimen: Serum/Plasma

Contents per Kit:

Test cassette with Desiccant Bag	25 Nos
Information for use (IFU)	1 No
Specimen transfer device	25 Nos

IVD

Mfg Date: Exp Date:

LOT:

Reg No.:

IRI. 1/07

2.3. Commercial presentation

There is one (1) approved commercial presentation as follows: one (1) test cassette in an aluminium pouch. 25 pouches in the carton box.

Additional contents include 25 droppers (specimen transfer devices), desiccant and package insert.

2.4. Items required but not submitted

Syringe with needles, vacutainer needles, alcohol swab, specimen collection containers (vacutainer tubes) and stop watch.

3. Storage instructions

3.1.1. Shelf-life

The approved shelf-life is 24 months.

3.1.2. Storage conditions

The recommended storage conditions is

- Store as packaged in the sealed pouch at temperature (4-30℃ or 40- 86℉).
- The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour.
- Prolonged exposure to hot and humid environment will cause product deterioration.

3.1.3. Shipping conditions

The recommended shipping conditions is 45^0C

4. Manufacturing site audit

The manufacturer of the device is Kas Biotech Limited, Plot# 11, GF09, Umoja Complex, Vingunguti, Industrial Area, Along Julius Nyerere Road, P. O Box 7856, Dar Es Salaam, Tanzania.

Quality audit of the manufacturing facility was conducted through site visit on 05.04.2023. The site was found to be compliant to ISO 13485 requirements.

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device was established through the following test parameters: analytical sensitivity and analytical specificity.

5.2. Clinical Performance

Clinical performance was conducted at Muhimbili National Hospital, Central Pathology Laboratory (CPL), Upanga West, and P. O. Box 65000, Dar es Salaam, Tanzania. The following parameters were tested; clinical sensitivity and clinical specificity.

Based on results of the performance studies, it was concluded that the test sensitivity and specificity is 99.2% and 99.0% respectively. The studies further concluded that KAS Hepatitis B (HBsAg) Rapid Test is capable of consistently producing accurate and reliable test output.

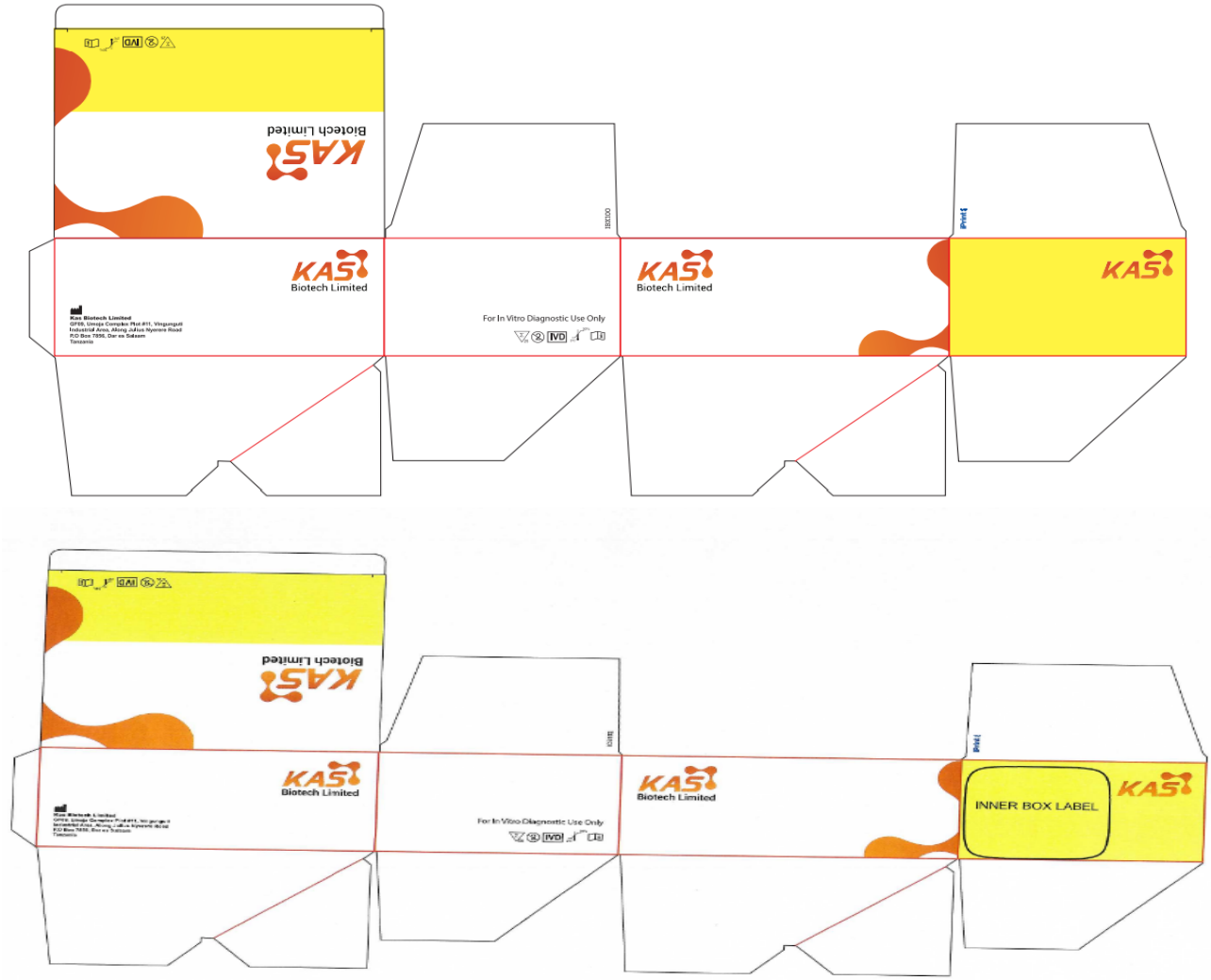
6. Product label and instructions for use

The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout and design. The label contains sufficient information for proper identification of the device and post marketing follow up of the product in the market.

The package insert (instructions for use) includes all the relevant information to ensure correct and safe use of the device by the intended user.

6.1. Primary pack

6.2. Secondary pack



6.3 Instructions for use/Package insert

See the IFU on the last page

7. Risk – Benefit Analysis

On basis of the data submitted, the current state of knowledge and compliance of the manufacturer to ISO 13485, the benefit of the product outweighs the risks associated with its use when used in accordance to the manufacturer instruction. KAS Hepatitis B (HBsAg) Rapid Test is recommended for registration.

8. Post-approval updates

8.1. Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
TMDA0022/IVD/0176/A2	25/08/2025	Changes in the dimension of the Box and improved quality of paper	YES	01/09/2025

8.2. Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response
No any recorded Adverse Event	NA	NA

8.3. Re-registration applications

NA

CHANGE HISTORY

Version number	Date	Description of update	Section(s) Modified	Approval date

KAS Biotech Limited **HBsAg Rapid Test Cassette (S/P)**

English

For professional and in vitro diagnostic use only.

[INTENDED USE]

The HBsAg Rapid Test kit is a lateral flow chromatographic immunoassay for the qualitative detection of Hepatitis B Surface Antigen in Human Serum/Plasma. It provides an aid in the diagnosis of infection with HepatitisB Virus.

[SUMMARY]

Hepatitis is a systemic viral disease primarily involving the liver. Hepatitis A Virus, Hepatitis B Virus (HBV), or Hepatitis C Virus are involved in most casesof acute viral hepatitis. HBV was discovered by Blumberg, et al. A complex antigen known as the Hepatitis B Surface Antigen (HBsAg) found on the surface of HBV is the first to be detected. The presence of HBsAg in a Serum/Plasma sample is indicative of an active HBV infection, either acute or chronic. In a typical HBV infection, HBsAg will be detected 2 to 4 weeks before the transaminase level becomes abnormal and 3 to 5 weeks before the patient develops symptoms or becomes jaundiced. HBsAg has four principal subtypes: adw, adr, ayw and ayr. Because of antigenic heterogeneity of the viral determinant, there are 10 major serotypes of HBV. The HBsAg Rapid Test Cassette is a rapid test to qualitatively detect the presence of HBsAg in Serum/Plasma specimens. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in Serum/Plasma.

[PRINCIPLE]

The HBsAg Rapid Test Cassette is an immunoassay based on the principleof the double antibody-sandwich technique. During testing, a Serum/Plasma specimen migrates upward by capillary action. The HBsAg if present in the specimen will bind to the labeled HBsAb antibody-dye conjugate. The immune complex is then captured on the membrane by the pre-coated HBsAb, and a visible colored line will show up in the test line region indicating a positive result. In the absence of HBsAg, a colored line will not form in the test line region indicating a negative result.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

[WARNINGS AND PRECAUTIONS]

- For in vitro diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handledin the same manner as an infectious agent.
- The used test cassette should be discarded according to federal, stateand local regulations.

[COMPOSITION]

The test cassette contains a membrane strip coated with anti-HBsAg antibody (HBsAb) on the test line, goat-anti-mouse IgG on the control line, and a dye pad which contains colloidal gold coupled with HBsAb. The quantity of tests was printed on the labeling.

Materials Provided

1.Test cassette 2. Dropper 3.Package insert

Materials Required But Not Provided

•Specimen collection container □Timer

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at temperature (4-30℃ or 40-86℉). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

[SPECIMEN]

- The test can be used to test Serum/Plasma specimens.
- Collect blood specimen (containing EDTA, citrate or heparin) by vein puncture following standard laboratory procedures.
- Separate the serum or plasma as soon as possible by centrifugationafter collecting.
- Store specimens at 2-8℃(36-46℉) if not tested immediately. Storespecimens at 2-8℃up to 7 days. The specimens should be frozen at -20℃(-4℉) for longer storage.
- Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugationbefore testing.
- Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

[TEST PROCEDURE]

Allow the test device and specimens to equilibrate to temperature (15-30℃or 59-86℉) prior to testing.

1. Remove the test cassette from the sealed pouch.
2. Hold the dropper vertically and transfer 3 full drops (approx. 100□l) of specimen to the "S" well of the test cassette, and then begin timing. See the illustration below.
3. Wait for colored lines to appear. Interpret the test results in 15 minutes. Do not read results after 20 minutes.

(The picture is for reference only, please refer to the material object.)

[INTERPRETATION OF RESULTS]

Positive **Negative** **Invalid**

(The picture is for reference only, please refer to the material object.) **Positive:*Two lines appear.** One colored line should be in the controlregion (C), and another apparent colored line adjacent should be in the testregion (T). This positive result indicates the presence of HBsAg.

Negative: One colored line appears in the control region (C). No line appears in the test region (T). This negative result indicates the absence of HBsAg.

Invalid: Control line fails to appear. Insufficient specimen volume or Incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test cassette.If the problem persists, discontinue using the lot immediately and contact your local distributor.

[QUALITY CONTROL]

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

[LIMITATIONS]

- The HBsAg Rapid Test is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of HBsAg in the blood.
- The results obtained from this test are intended to be an aid in diagnosis only. Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
- A negative test result indicates that HBsAg is either not present or at levels undetectable by the test.

[PERFORMANCE CHARACTERISTICS]

Sensitivity

The HBsAg Rapid Test Cassette will detect the concentration of HBsAg is equal to or greater than 5IU/ml (calibrated against WHO 2nd IS 00/588).

Acc urac y

Agreement with Commercial HBsAg Rapid Test

A side-by-side comparison was conducted using the HBsAg Rapid Test and commercially available HBsAg rapid tests. 1044 clinical specimens from three hospitals were evaluated with the HBsAg Rapid Test Test and the commercial kit. The following results are tabulated from these clinical studies:

		Commercial HBsAg Rapid Test		Total
		Positive	Negative	
	Positive	389	2	391
	Negative	0	653	653
Total		389	655	1044

The agreement between these two devices is 100% for positive specimens, and 99.7% for negative specimens. This study demonstrated that the HBsAg Rapid Test is substantially equivalent to the commercial device.

Agreement with ELISA

A total of 500 samples from susceptible subjects were tested with the HBsAg Rapid Test and by a commercial HBsAg ELISA kit. Comparison for all subjects is showed in the following table:

		ELISA		Total
		Positive	Negative	
	Positive	148	0	148
	Negative	2	350	352
Total		150	350	500

A statistical comparison was made between the results yielding a clinical sensitivity of 98.7%, a clinical specificity of 100% and an accuracy of 99.6%.

Cross-Reactivity and Interference

1. Other common causative agents of infectious diseases were evaluated for cross reactivity with the test. Some positive serum specimens of other common infectious diseases were spiked into the HBsAg positive and negative specimens and tested separately. No cross reactivity wasobserved with specimens from patients infected with HIV, HAV, HCV, HTLV, CMV and TP.
2. Potentially cross-reactive endogenous substances including common serum components, such as lipids, hemoglobin, bilirubin, were spiked at high concentrations into the HBsAg positive and negative specimensand tested, separately. No cross reactivity or interference was observed to the device.

Analytes	Conc.	Specimens	
		Positive	Negative
Albumin	20mg/ml	+	-
Bilirubin	20µg/ml	+	-
Hemoglobin	15mg/ml	+	-
Glucose	20mg/ml	+	-
Uric Acid	200µg/ml	+	-
Lipids	20mg/ml	+	-

3. Some other common biological analytes were spiked into the HBsAg positive and negative specimens and tested separately. No significant interference was observed at the levels listed in the table below.

Analytes	Conc. (µg/ml)	Specimens	
		Positive	Negative
Acetaminophen	200	+	-
Acetoacetic Acid	200	+	-
Acetylsalicylic Acid	200	+	-
Ampicillin	200	+	-
Ascorbic Acid	200	+	-
Atropine	200	+	-
Benzoylecgonine	100	+	-
Caffeine	200	+	-
EDTA	800	+	-
Ethanol	1.0%	+	-
Gentisic Acid	200	+	-
β - Hydroxybutyrate	20,000	+	-
Methanol	10.0%	+	-
Phenothiazine	200	+	-
Phenylpropanolamine	200	+	-
Salicylic Acid	200	+	-
Tetracycline	200	+	-

[Bibliography]

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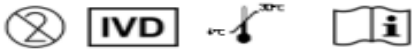

Index of Symbol

Do not reuse	For in vitro diagnostic use only
Store between 4-30°C	Consult instructions for use
Caution	Lot number
Use by	Contains sufficient for <n> tests
Keep away from sunlight	Keep dry
Manufacturer	Do not use if package is damaged

Version No.: 00

Kas Biotech Limited
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