THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR SMART HCV AB RAPID TEST KIT

Version number 2.0, 29/04/2023

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1.Introduction

Smart is a class C in-vitro diagnostic device belonging to the Microbiology specialty category. Smart is approved in Tanzania as a kit for use by healthcare professionals.

1.1. Administrative Information

Registration number	TAN 21 MDR 0445
Brand name (if relevant)	SMART
Common name	HCV Ab Rapid Test Kit
Class of the device and rule applied	Class D according to Rule 1 of Classification for In Vitro Diagnostic Devices
GMDN code and term	48366 Hepatitis C virus total antibody IVD, kit, chemiluminescent assay
Name and complete address of the Market Authorization Holder	KS Global Enterprises Tanzania Limited, Lindi/Congo Street Kariakoo, P.O Box 7152, Dar es salaam. Telephone: 0788 329566 Email: ksglobal@yahoo.com
Name and address(es) of local responsible person (LRP).	KS Global Enterprises Tanzania Limited, Lindi/Congo Street Kariakoo, P.O Box 7152, Dar es salaam. Telephone: 0788 329566 Email: ksglobal@yahoo.com

1.2. Assessment Procedure

The application for registration of Smart was submitted on 05/07/2021. The product underwent full registration procedure assessment. Assessment was completed in 1 round of evaluation. Smart was registered on 09/01/2021

2. Technical information

2.1. Intended use

The intended use of Smart as declared by the manufacturer and approved by TMDA is to detect antibodies (IgG, IgM, and IgA) anti- Hepatitis C virus (HCV) 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 HCV. Smart is approved for use in healthcare settings by trained professionals only.

2.2. Device details and features

Smart has been registered as a kit which consists of test strip, pipette dropper, desiccant, buffer and package insert.

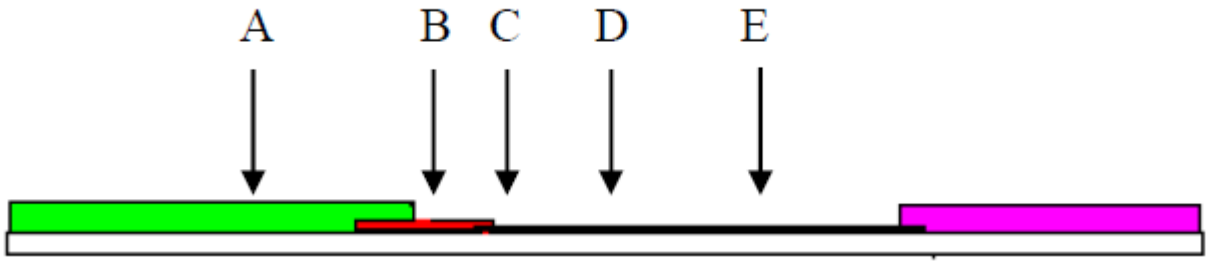
Smart is an in vitro diagnostic device. It is used for screening or aid diagnosis of Hepatitis C virus (HCV). Smart operates by principle of the double antigen–sandwich technique. The test out-put is qualitative.

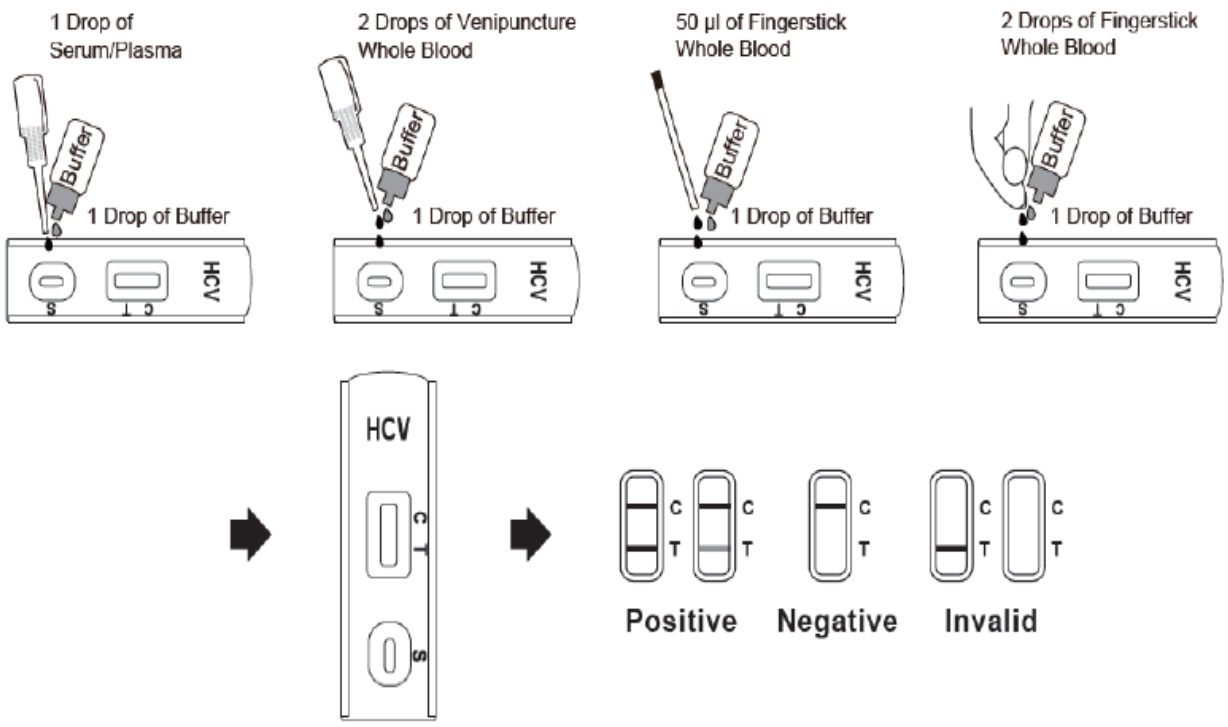
The type of specimen used is whole blood/serum/plasma and is collected by venous blood collection, capillary blood specimen collection.

Device description

The test strip consists of: 1) a burgundy-colored conjugate pad containing HCV antigens conjugated with colloidal gold (HCV Ag conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated HCV antigens, and the C band is pre-coated with goat anti-rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the strip, the specimen migrates by capillary action across the strip. The antibodies: either the IgG, the IgM, or the IgA, to HCV if present in the specimen will bind to the HCV Ag conjugates. The immunocomplex is then captured on the membrane by the pre-coated HCV antigens, forming a burgundy colored T band, indicating a HCV Ab positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless the presence of any antibodies to HCV. Otherwise, the test result is invalid and the specimen must be retested with another device.

Pictorial Diagram





2.3. Commercial presentation

The test kit is not automated and does not require any additional instrument.

2.4. Items required but not submitted

a) Specimen collection containers
b) Lancets (for fingerstick whole blood only)
c) Centrifuge (for plasma only)
d) Timer
e) Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

3. Storage instructions

3.1.1. Shelf-life

The approved shelf-life is 24 months.

3.1.2. Storage conditions

The recommended storage conditions are 2°C - 30°C.

3.1.3. Shipping conditions

The recommended shipping conditions is 45°C.

4. Manufacturing site audit

The manufacturer of the device is,
Zhejiang Orient Gene Biotech Company Limited,
679#, East Yangguang Avenue, Dipu Town, Anji,
Zhejiang 313300,
Peoples Republic of China.

Quality audit of the manufacturing facility was conducted through site visit, on 20-21/03/2019. 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: precision (repeatability and reproducibility), analytical sensitivity, analytical specificity.

5.2. Clinical Performance

Clinical performance was conducted at Anji Traditional Medicine Hospital. Parameters were tested for analytical sensitivity and specificity.

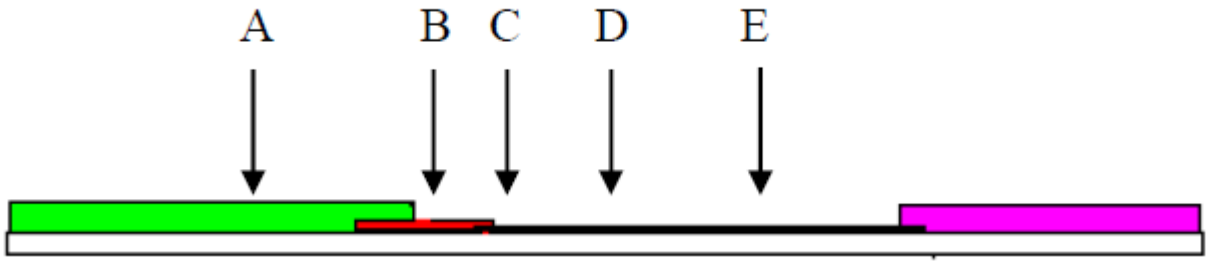
Based on results of the performance studies, it was concluded that the test sensitivity and specificity is 99.5% and 99.4% respectively. The studies further concluded that Smart is capable of consistently producing accurate and reliable test output.

6. Product label and instructions for use

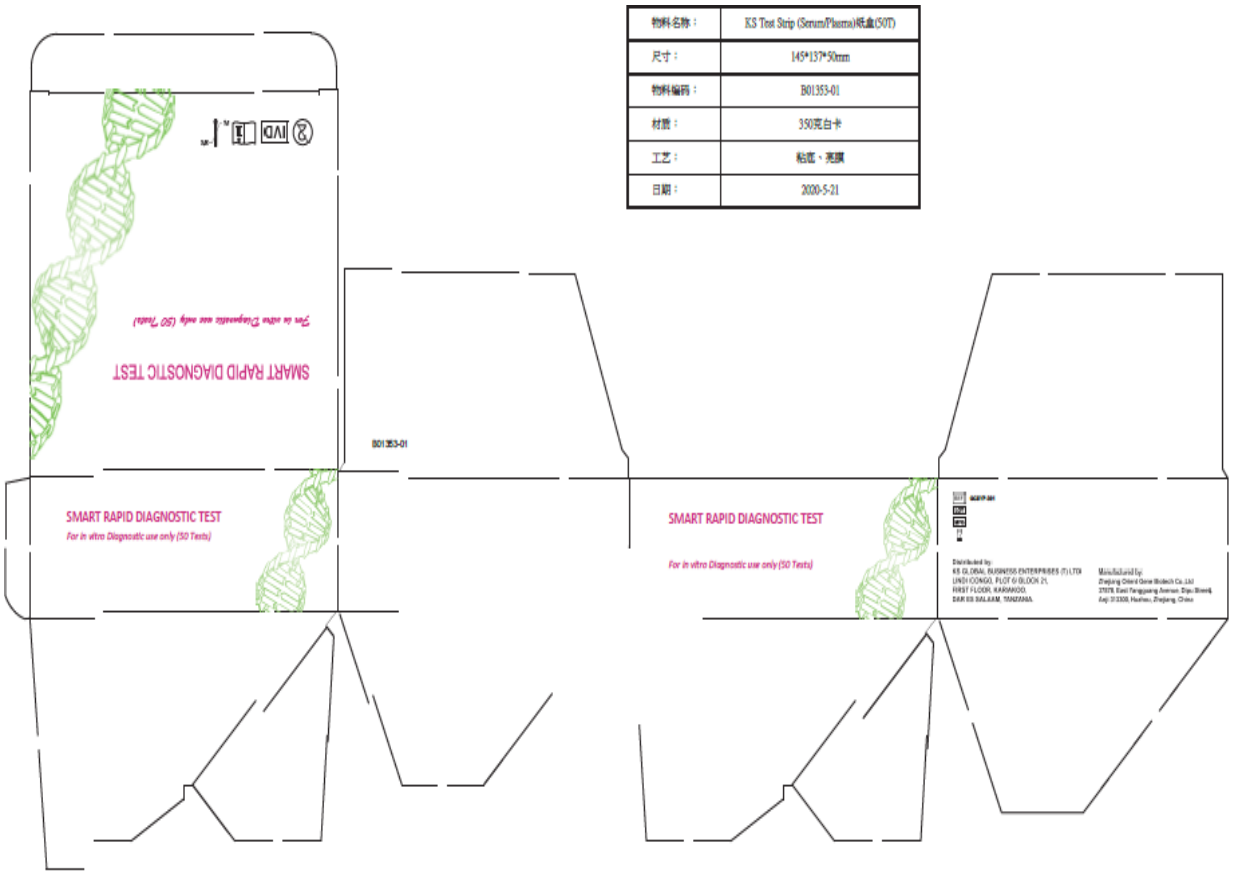
The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout and design. The label contains sufficient information for proper identification of the device and post marketing follow up of the product.

The instructions for use include all the relevant information to ensure correct and safe use of the device by healthcare providers.

6.1. Primary pack



6.2. Secondary pack



6.3 Instructions for use/Package insert

Instructions for use can be accessed by clicking here.

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's instruction. SMART HCV Ab Rapid Test Kit was recommended for registration.

8. Post-approval updates

8.1. Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
NA				

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

Type of feedback	Impact	Response
No recorded Adverse Event	NA	

8.3. Re-registration applications

NA

CHANGE HISTORY

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

HBsAg Rapid Test Strip (Serum/Plasma)

INTENDED USE

The HBsAg Rapid Test Strip is a lateral flow chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) in human 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.

INTRODUCTION

Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. The presence of HBsAg in serum or plasma is an indication of an active Hepatitis B infection, either acute orchronic. In a typical Hepatitis B infection, HBsAg will be detected 2 to 4 weeks before the ALT level becomes abnormal and 3 to 5 weeks before symptoms or jaundice develop. HBsAg has four principal subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of Hepatitis B virus.
The HBsAg Test Strip (Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAg in serum or plasma specimens. The test utilises a combination of double monoclonal antibodies to selectively detect elevated levels of HBsAg in serum or plasma.

PRINCIPLE

The HBsAg Rapid Test Strip is a lateral flow chromatographic immunoassay based on the principle of the double antibody–sandwich technique. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the test. During testing, Hepatitis B Surface Antigen in the serum or plasma specimen reacts with the particle coated with anti-HBsAg antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg 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 the proper volume of specimen has been added and membrane wicking has occurred.

PRODUCT CONTENTS

The HBsAg Test Strip (Serum/Plasma) containing anti-HBsAg antibodies particles and anti-HBsAg antibodies coated on the membrane.

MATERIALS SUPPLIED

1. Test Strip
2. Desiccant
3. Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Specimen collection containers.
3. Centrifuge (for plasma only)

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

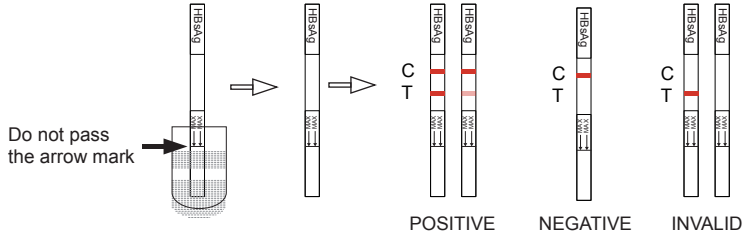
1.For professional In Vitro diagnostic use only. Do not use after expiration date.
2.Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3.Do not use it if the tube/pouch is damaged or broken.
4.Test is for single use only. Do not re-use under any circumstances.
5.Handle all specimens as if they contain infectious agents.Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6.Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7.Humidity and temperature can adversely affect results .
8.Do not perform the test in a room with strong air flow, ie. electric fan or strong airconditioning.

SPECIMEN COLLECTION

1.HBsAg Rapid Test Strip (Serum/Plasma) can be performed using either serum or plasma.
2.Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used.
3.Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.specimens may be stored at 2-8℃ for up to 3 days. For long term storage, specimens should be kept below -20℃.
4.Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5.If specimens are to be shipped ,they should be packed in compliance with usual regulations for transportation of aetiological agents.

TEST PROCEDURE

Allow test strip, specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
1.Remove the test strip from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2.Dip the strip into the specimen for at least 10 seconds until thoroughly wet. Don't allow the specimen reach above the level indicated by the arrows on the strip.Meanwhile, set up time.
3.Remove the strip from the specimen, and place it on a flat, dry surface.
4.Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).
NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).
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 with a new test strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.
Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1.Though the HBsAg Rapid Test Strip is a reliable screening assay, it should not be used as a sole criterion for diagnosis of HBV infection.

HBsAg Rapid Test Strip (Serum/Plasma)

2. The HBsAg Rapid Test Strip is limited to the qualitative detection of HBsAg in human serum or plasma. The intensity of the test band does not have linear correlation with HBsAg titer in the specimen.
3. A negative test result does not preclude the possibility of exposure to or infection with HBV. Infection through recent exposure (seroconversion) to HBV may not be detectable.
4. A negative result can occur if the quantity of HBsAg present in the specimen is below the detection limits of the assay (lower than1 ng/mL), or the HBsAg that are detected are not present during the stage of disease in which a sample is collected.
5. Interference due to heterophile antibodies, Rheumatoid Factors and other nonanalyte substances in patient's serum,capable of binding antibodies multivalently and providing erroneous analyte detection in immunoassays, has been reported in various studies. Both laboratory professionals and clinicians must be vigilant to this possibility of antibody interference. Results that appear to be internally inconsistent or incompatible with the clinical presentation should invoke suspicion of the presence of an endogenous artifact and lead to appropriate in vitro investigative action.
6.This kit is intended ONLY for testing of individual samples. Do not use it for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.
7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Sensitivity:
The HBsAg Rapid Test Strip (Serum/Plasma) has been tested with a sensitivity panel ranging from 0 to 300 ng/mL. All 10 HBsAg subtypes produced positive results on the HBsAg Rapid Test Strip (Serum/Plasma). The test can detect 5ng/mL of HBsAg in 10 minutes, and 1 ng/mL of HBsAg in 15 minutes.
Specificity:
Antibodies used for the HBsAg Rapid Test Strip (Serum/Plasma) were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of the HBsAg Rapid Test Strip (Serum/Plasma) was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

HBsAg Rapid Test Strip vs. EIA test

Method		EIA		Total Results
HBsAg Rapid Test Strip	Results	Positive	Negative	
	Positive	345	5	350
	Negative	2	980	982
Total Results		347	985	1332

Relative sensitivity: 99.4%
Relative specificity: 99.5%
Accuracy: 99.5%

REFERRENCE

1. Blumberg, B. S. The Discovery of Australian Antigen and its relation to viral hepatitis. Vitro. 1971; 7: 223