THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR SMART (HIV 1/2 RAPID TEST CASSETTE)

Version number 2.0, 18.05.2026

TMDA Headquarters, Plot No. 56/1, Block E, Kisasa B Centre, Hombolo Road, P. O. Box 1253, Dodoma – Tanzania, Telephone: +255 (26) 2961989/2061990/+255 (22) 2450512/2450751/2452108, Email: info@tmda.og.tz, Website: **www.tmda.go.tz**

Toll free: 0800110084

1. Introduction

Smart is a class D in-vitro diagnostic device belonging to the immunology specialty category. It is approved in Tanzania as a kit for use in adults, children, elderly etc. by healthcare professionals.

1.1. Administrative Information

Registration number	TAN 25 MDR 0039
Brand Name (if relevant)	Smart
Common name	HIV 1/2 Rapid Test Cassette
Class of the device and rule applied	Class D as per Rule 1 for classification of In Vitro Diagnostic Devices.
GMDN code and term	65847, HIV1/HIV2 antibody IVD, kit, rapid ICT, clinical
Name and complete address of the Market Authorization Holder	KS Global Business Enterprise(T) LTD (8308) Lindi/Congo street Kariakoo Dar-es-salaam, Tanzania Email: ksglobal2016@yahoo.com Tel: 0788329566
Name and address(es) of local responsible person (LRP).	KS Global Business Enterprise(T) LTD (8308) Lindi/Congo street Kariakoo Dar-es-salaam, Tanzania Email: ksglobal2016@yahoo.com Tel: 0788329566

1.2. Assessment Procedure

The application for registration of Smart was submitted on 21.02.2024. The product underwent full assessment. Assessment was completed in 2 rounds of evaluation. Smart was registered on 19.03.2025.

2. Technical information

2.1. Intended use

The intended use of Smart as declared by the manufacturer and approved by TMDA is a rapid chromatographic immunoassay with a double antigen system for the qualitative detection of antibodies to HIV-1 and/or HIV-2 in 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 HIV. Any reactive specimen with the HIV 1/2 Ab Rapid Test Cassette must be confirmed

with alternative testing method(s). Smart is approved for use in healthcare settings, point of care by trained professionals only.

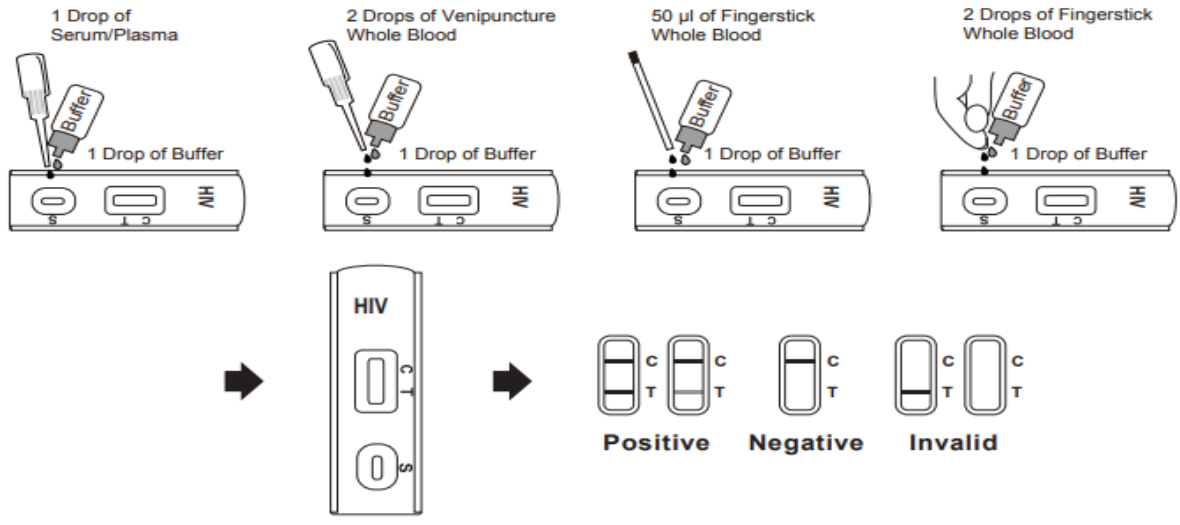
2.2. Device details and features

Smart is a single device with no additional components or accessories. Smart has been registered as a kit which consists of Test Cassette, Pipette Dropper, Desiccant. Buffer and Package Insert.

Smart is a manually operated device. It is used for aid diagnosis, screening of HIV. Smart operates is a lateral flow chromatographic immunoassay based on the 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 and finger prick

Product description
The HIV 1/2 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibodies to HIV-1 and/or HIV-2 in whole blood, serum or plasma specimens. The test utilizes gold conjugate and multiple recombinant HIV proteins to selectively detect antibodies to the HIV 1/2 in whole blood, serum or plasma. The HIV 1/2 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The membrane is coated with recombinant HIV recombinant antigens on the test line region of the device. When a specimen is applied at one end of the membrane, it reacts with HIV recombinant antigen coated gold conjugate in the test



2.3. Commercial presentation

There are one (1) approved commercial presentations as follows: One (1) Test Cassette, Pipette Dropper and Desiccant in primary foil pouch. 25 number of units in secondary pack are placed in secondary carton box.

Additional contents include buffer and package insert

2.4. Items required but not submitted

- Specimen collection containers
- Lancets (for fingerstick whole blood only)
- Centrifuge (for plasma only)
- Timer
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

3. Storage instructions

3.1.1. Shelf-life

24 months.

3.1.2. Storage conditions

The recommended storage conditions can be stored at room temperature or refrigerated (2-30°C). DO NOT FREEZE. Do not use beyond the expiration date.

3.1.3. Shipping conditions

The recommended shipping conditions is 2-30^{0}C

4. Manufacturing site audit

The manufacturer of the device is Zhejiang Orient Gene Biotech Co., Ltd, 3787#, East Yangguang Avenue, Dipu Street Anji, 313300 Huzhou, Zhejiang, People's Republic of China. Tel: +86-572-5226222

Quality audit of the manufacturing facility was conducted through site visit on 20th – 21st March, 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 and analytical specificity.

5.2. Clinical Performance

Clinical performance was conducted at National Public Health laboratory a report that was signed on 5th April, 2024. The following parameters were tested; precision (repeatability and reproducibility), clinical sensitivity and clinical specificity.

Based on results of the performance studies, it was concluded that the test sensitivity and specificity is 100% and 100% respectively. The studies further concluded that Smart is capable of consistently producing accurate and reliable test output.

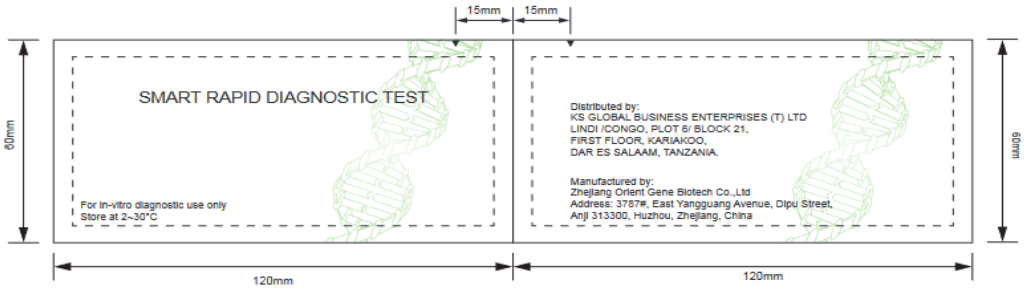
6. Product label and instructions for use

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 in the market.

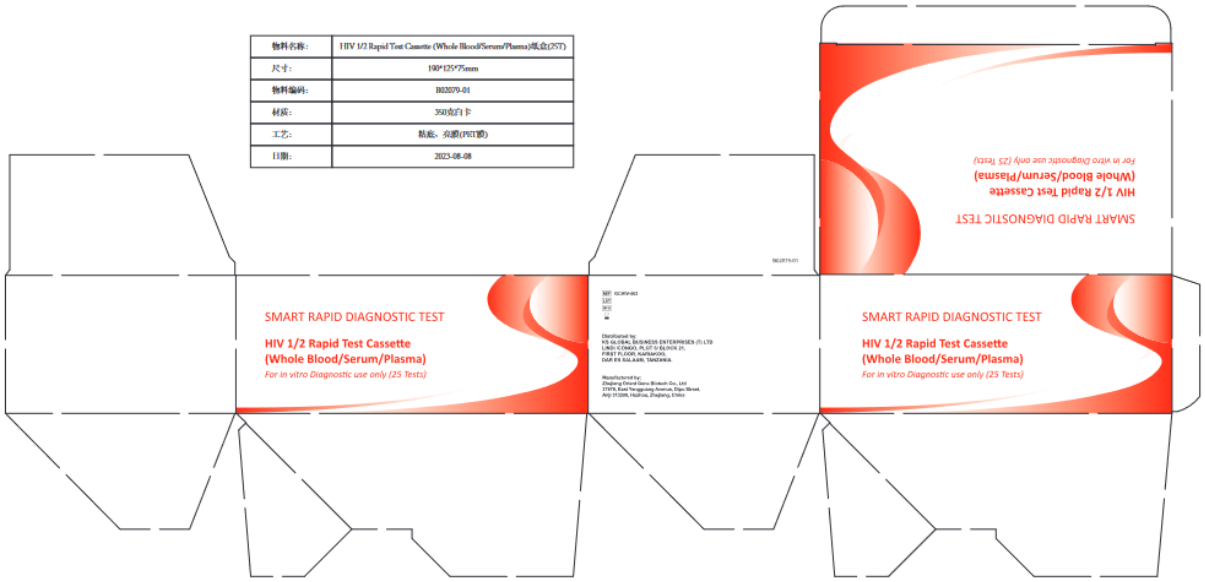
The instructions for use includes all the relevant information to ensure correct and safe use of the device by intended user.

6.1. Primary pack

物料名称:	KS Pouch
尺寸:	120*60mm
物料编码:	B11093-01
材质:	PET12/AL7/CPP55
工艺:	彩色印刷
日期:	2020-5-12



6.2. Secondary pack



6.3 Instructions for use/Package insert

See it 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. Smart is recommended for registration.

8. Post-approval updates

8.1. Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
NA	NA	NA	NA	NA

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

HIV 1/2 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma)

INTENDED USE

The HIV 1/2 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay with a double antigen system for the qualitative detection of antibodies to HIV-1 and/or HIV-2 in 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 HIV. Any reactive specimen with the HIV 1/2 Ab Rapid Test Cassette must be confirmed with alternative testing method(s).

INTRODUCTION

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virion is surrounded by a lipid envelope that is derived from the host cell membrane. Several viral glycoproteins are on the envelope. Each virus contains two copies of positive-sense genomic RNAs. HIV-1 has been isolated from patients with AIDS and AIDS-related complex,and from healthy people with a high potential risk for developing AIDS.[1] HIV-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals.[2] Both HIV-1 and HIV-2 elicit an immune response.[3] Detection of HIV antibodies in serum or plasma is the most efficient and common way to determine whether an individual has been exposed to HIV and to screen blood and blood products for HIV.[4] Despite the differences in their biological characters, serological activities and genome sequences, HIV-1 and HIV-2 show strong antigenic cross-reactivity.[5] Most HIV-2 positive sera can be identified by using HIV-1 based serological tests.

The HIV 1/2 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibodies to HIV-1 and/or HIV-2 in whole blood, serum or plasma specimens. The test utilizes gold conjugate and multiple recombinant HIV proteins to selectively detect antibodies to the HIV 1/2 in whole blood, serum or plasma.

PRINCIPLE

The HIV 1/2 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The membrane is coated with recombinant HIV recombinant antigens on the test line region of the device. When a specimen is applied at one end of the membrane, it reacts with HIV recombinant antigen coated gold conjugate in the test. The mixture then migrates chromatographically by capillary action and reacts with the recombinant HIV recombinant antigens on the membrane in the test line region.

If the specimen contains antibodies to HIV-1 or HIV-2, a colored line will appear in the test line region, showing a positive result. The absence of the colored test line indicates that the specimen does not contain the anti-HIV antibodies, showing a negative result. A colored line will always appear at the control line region to serve as a procedural control. This indicates if the proper volume of specimen has been added and that membrane wicking has occurred.

PRODUCT CONTENTS

The HIV 1/2 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) contains HIV recombinant antigen coated particles and HIV recombinant antigens coated on the membrane.

MATERIALS SUPPLIED

1. Test Cassette 2 Pipette Dropper 3.Desiccant 4.Buffer 5.Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

1.Specimen collection containers 2.Lancets (for fingerstick whole blood only)
3.Centrifuge (for plasma only) 4.Timer
5.Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

STORAGE AND STBILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette 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. an electric fan or strong airconditioning.

SPECIMEN COLLECTION

1.The HIV1/2 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.

2.To collect Fingerstick Whole Blood specimens:

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube:
  - Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.
- Add the Fingerstick Whole Blood specimen to the test device by using hanging drops:
  - Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
  - Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test device, or move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).

3.Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

4.Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

5.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.

TEST PROCEDURE

Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1.Remove the test device 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. Place the test device on a clean and level surface.

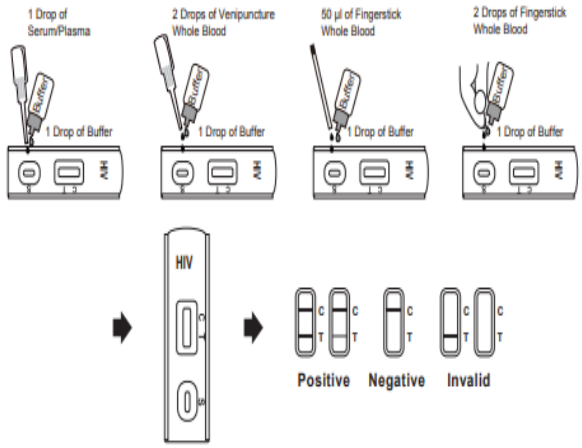
For Serum or Plasma Specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 30 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

For Venipuncture Whole Blood Specimens: Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

For Fingerstick Whole Blood Specimens: Allow 2 hanging drops of fingerstick whole blood (approximately 50 µL) to fall into the center of the specimen well (S) on the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

3. Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes.

HIV 1/2 Ab Rapid Test Cassette
(Whole Blood/Serum/Plasma)



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).

*NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of HIV antibodies in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

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 cassette. 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. The HIV 1/2 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of antibodies to HIV-1 and/or HIV-2 in whole blood, serum or plasma.
2. The HIV 1/2 Ab Rapid Test Cassette is limited to the qualitative detection of antibodies to HIV-1 or HIV-2 in human whole blood, serum or plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable HIV-1 or HIV-2 antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with HIV-1 or HIV-2.
4. A negative result can occur if the quantity of the HIV-1 or HIV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Although a positive result may indicate infection with HIV-1 or HIV-2 virus, a diagnosis of AIDS can only be made on clinical grounds, if an individual meets the case definition for AIDS established by the Centers fir Disease Control. For samples repeatedly tested as positive, more specific supplemental tests must be performed.
6. Immunochomatographic testing alone cannot be used to diagnose AIDS even if the antibodies against HIV-1 and/or HIV-2 are present in a patient specimen.
7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
8. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

PERFORMANCE CHARACTERISTICS

Sensitivity: The test has been compared with a leading commercial HIV EIA test using clinical specimens. Results showed the HIV 1/2 Ab Rapid Test Cassette is very sensitive to HIV-1 and/or HIV-2 antibodies.

Specificity: The specificity is comparable to a leading commercial HIV EIA test. The test is highly specific for anti-HIV-1 and/or HIV-2 when compared to a leading commercial HIV EIA test.

The HIV 1/2 Ab Rapid Test Cassette vs. EIA test

Method		EIA		Total Results
HIV 1/2 Rapid Test	Results	Positive	Negative	
	Positive	210	2	212
	Negative	1	1050	1051
Total Results		211	1052	1263

Relative sensitivity:99.5%
Relative specificity: 99.8%
Accuracy: 99.8%

REFERRENCE

1. Arya SK, Beaver B, Jagodzinski L, Ensoli B, Kanki PJ,Albert J, Fenyo EM, Biberfeld G, Zagury JF and Laure F. New human and simian HIV-related retroviruses possess functional transactivator (tat) gene. Nature (1987) 328:548-550.
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3. Chang SY, Bowman BH, Weiss JB, Garcia RE and White TJ. The Origin of HIV-1 isolate HTLV-IIIB. Nature (1993) 3:363:466-9.
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5. Greenberg AE, Wiktor SZ, DeCock KM, Smith P, Jaffe HW and Dondero TJ Jr. HIV-2 and natural protection against HIV-1 infection. Science (1996) 272:1959-1960