w THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR MAXLINE HIV 1 & 2 TRI-LINE RAPID ANTIBODY TEST KIT FOR HIV 1/2

Version number 2.0, 18.05.2026

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Introduction

MaxLINE HIV 1&2 Tri-line Rapid antibody test Kit for HIV 1&2 is a class D in-vitro diagnostic device belonging to the Infectious disease specialty category. MaxLINE HIV 1&2 Tri-line is approved in Tanzania as a kit by healthcare professionals.

1.1. Administrative Information

Registration number	TAN 25 MDR 0283
Brand Name (if relevant)	MaxLINE HIV 1&2 Tri-line
Common name	Rapid antibody test Kit for HIV 1 & 2
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	Avecon Healthcare Pvt. Ltd., Plot No-338, Industrial Growth Centre, Sector-2, Saha, Ambala (Haryana), INDIA
Name and address(es) of local responsible person (LRP).	Malulu Company Ltd, P.O.BOX 850 Kiusa Line, Plot No. 331 CCC Kilimanjaro, Tanzania.

1.2. Assessment Procedure

The application for registration of MaxLINE HIV 1&2 Tri-line was submitted on 16.04.2024. The product underwent full assessment. Assessment was completed in 05 rounds of evaluation. MaxLINE HIV 1&2 Tri-line was registered on 28.11.2025.

2. Technical information

2.1. Intended use

The intended use of MaxLINE HIV 1&2 Tri-line as declared by the manufacturer and approved by TMDA is a rapid chromatographic immunoassay for the qualitative detection of antibodies to HIV-1 & HIV-2, in human serum, plasma or whole blood to aid in the diagnosis of HIV infection. MaxLINE HIV 1&2 Tri-line is approved for use in healthcare settings, point of care by trained professionals.

2.2. Device details and features

MaxLINE HIV 1&2 Tri-line has been registered as a kit which consists of individual pouches containing test cassette, sample droppers, desiccant, bottle buffer solution, Instructions for use, Alcohol swabs, Sterile lancets.

MaxLINE HIV 1&2 Tri-line is an in vitro diagnostic device. It is used for screening and diagnosis of HIV-1 & HIV-2, in human serum, plasma or whole blood to aid in the diagnosis of HIV infection operates by immunochromatographic principle. The test out-put is qualitative.

The type of specimen used is Whole Blood/Serum/Plasma and is collected by taking a small sample of either venous whole blood, fingerstick whole blood, serum, or plasma from the patient.

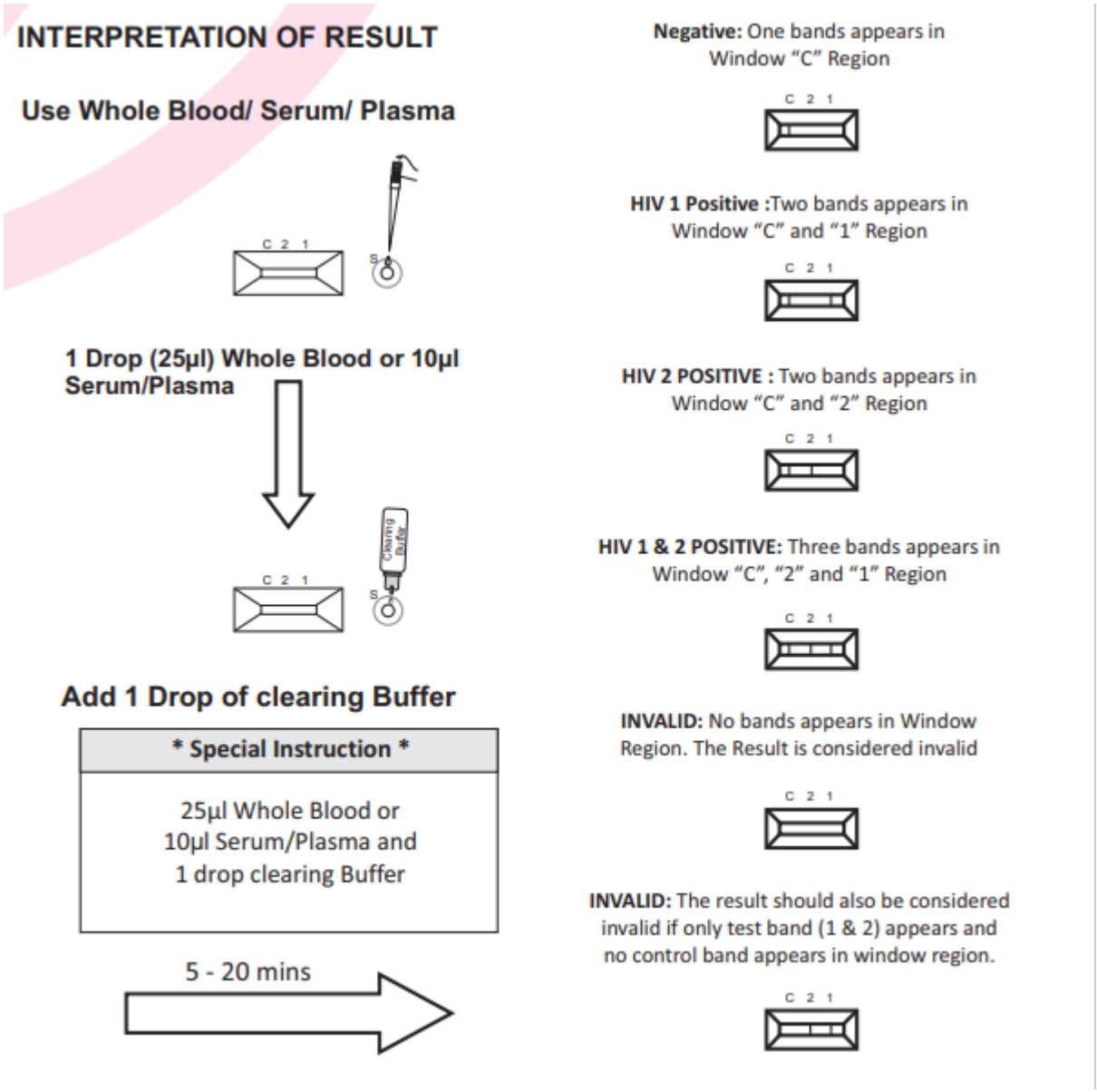
Device description

MaxLINE HIV 1&2 Tri-line is a rapid immunochromatographic direct binding test for the visual detection of HIV antibodies in venous whole blood, fingerstick whole blood, serum or plasma samples in the diagnosis of HIV infection.

MaxLINE HIV 1&2 Tri-line adopts double antigen sandwich method. When the specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the antigen-dye conjugate, and flows across the HIV antigen pre-coated membrane. 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.

When the HIV antibody levels are at or above the detection limit of the test, HIV antibodies in the specimen bind to the antigen-dye conjugate and are captured by antigen immobilized in the test region (T) of the device. This produces a colored test band and indicates a positive result. If no HIV antibodies are present or below the detection limit of the assay, no colored band will be visible in the test region (T) of the device. This indicates a negative result. To serve as a procedure control, a colored line will appear at the control region (C), if the test has been performed properly.

Pictorial Presentation



2.3. Commercial presentation

There are 5 approved commercial presentations as follows: One test cassette in a pouch with a desiccant. 10, 20,25, 30 or 50 pouches are placed in the carton boxes. Each carton box may have one of ten different product codes depending on the contents inside; AVHIV3WB-10, AVHIV3WB-20, AVHIV3WB-25, AVHIV3WB- 30 and AVHIV3WB-50.

Additional contents include;

a) Buffer
b) Sample Dropper
c) Product insert

2.4. Items required but not submitted

a) Specimen collection containers
b) Centrifuge (For serum/plasma separation)
c) Stop Watch

3. Storage instructions

3.1.1. Shelf-life

24 months.

3.1.2. Storage conditions

The recommended storage conditions: Store as packaged in the sealed pouch either for the kit and buffer is at either 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 of the HIV 1 & 2 Triline Rapid Test at three types of different simulation conditions (5°C ± 3°C, 40°C ± 1°C and 55°C ± 1°C) for at least 50 days in each condition.

4. Manufacturing site audit

The manufacturer of the device is Avecon Healthcare Pvt. Ltd. Plot No-338, Industrial Growth Centre, Sector-2, Saha, Ambala (Haryana) India.

Quality audit of the manufacturing facility was conducted through site visit on 10^{th} -11^{th} October, 2024. 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: Accuracy, trueness, precision (repeatability and reproducibility), analytical sensitivity and analytical specificity.

5.2. Clinical Performance

Clinical performance was conducted at Kilimanjaro Clinical Research Institute (KCRI) Biotechnology Laboratory, Box 2236, Moshi, Tanzania.

The following parameters were tested; clinical sensitivity and clinical specificity. Based on results of the performance studies, it was concluded that the test clinical sensitivity and clinical specificity is 100 % and 100 % respectively. The studies further concluded that MaxLINE HIV 1&2 Tri-line 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 user manual, package insert, instructions for use includes 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 but also on the last page.

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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. MaxLINE HIV 1&2 Tri-line was 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

AVECON
Transforming Research Into Innovations

One Step Rapid Test for HIV 1 & 2

MaxLINE HIV 1 2 Tri-line

Serum/Plasma/Whole Blood Test Protocol

ORDERING INFORMATION

Ref. No.	Pack Size
AVHIV3WB-10	10 Tests
AVHIV3WB-20	20 Tests
AVHIV3WB-25	25 Tests
AVHIV3WB-30	30 Tests
AVHIV3WB-50	50 Tests

NOTE : 10T, 20T, 25T, 30T Pack Sizes are not available for domestic trade.

INTENDED USE

The **HIV 1 2 Tri-line** Human Immunodeficiency Virus Rapid Test Device (Serum/Plasma/ Whole Blood) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to HIV-1 & HIV-2, in human serum, plasma or whole blood to aid in the diagnosis of HIV infection.

PRODUCT FEATURES:

1. Lateral Flow Immuno Chromatography Assay.
2. Double Antigen sandwich Principle.
3. Detects IgG and IgM Antibodies against HIV 1 & HIV 2.
4. Relative Sensitivity : 100 %
5. Relative Specificity : 99.8 %.
6. Has been compared with HIV ELISA tests and the correlation between the systems is 99%.

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 high potential risk for developing AIDS. HIV-1 were first recognized in 1990 and HIV-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals. HIV-1 & 2 all elicit immune responses. Detection of HIV antibodies in serum, plasma is the most efficient and common way to determine whether an individual has been exposed to HIV. Despite the differences in their biological characters, serological activities and genome sequences, HIV-1 & 2 show strong antigenic cross-reactivity. Most HIV-2 positive sera can be identified by using HIV-1 based serological tests.The HIV-1 & 2 Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibodies to HIV-1 & 2 in serum or plasma specimen.

PRINCIPLE

The HIV-1 2 Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibodies to HIV-1 & 2 in serum or plasma. The membrane is pre-coated with recombinant HIV antigens in the test line regions, 1 and 2. The 1 test line is pre-coated with HIV-1 antigen and the 2 test line is pre-coated with HIV-2 antigen. During testing, the serum or plasma specimen reacts with the mixture of HIV-1 envelope and core antigens and HIV-2 envelope antigen that are coated on colored particles in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with recombinant HIV antigen on the membrane in the test line region. If the specimen contains antibodies to HIV-1 one colored line will appear in the test line region; if the specimen contains antibodies to HIV-1 & 2 two colored lines will appear in the test line region. Both indicate a positive result. If the specimen does not contain HIV-1 & 2 antibodies, no colored line will appear in the test line region indicating 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.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (4-30°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.

KIT CONTAINS

Ref. No.	Pack Size	Test Device	Buffer Vial	Product Insert
AVHIV3WB-10	10 Tests	10 Nos.	1 No.	1 No.
AVHIV3WB-20	20 Tests	20 Nos.	1 No.	1 No.
AVHIV3WB-25	25 Tests	25 Nos.	1 No.	1 No.
AVHIV3WB-30	30 Tests	30 Nos.	2 Nos.	1 No.
AVHIV3WB-50	50 Tests	50 Nos.	3 Nos.	1 No.

MATERIALS

1. Materials Provided

Each kit contains :

a) Individually packed test device
b) Buffer
c) Sample Dropper
d) Product insert

2. Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (For serum/plasma separation)
- Stop Watch

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after expiration date
2. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested
3. Do not eat, drink or smoke in the area where the specimens or kits are handled
4. 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
5. The used test should be discarded according to local regulations.
6. Humidity and temperature can adversely affect results.

SPECIMEN COLLECTION AND PREPARATION

1. The HIV 1 2 Tri-line Human Immunodeficiency Virus Rapid Test Device(Serum/Plasma/Whole Blood) can be performed using serum, plasma or whole blood.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimen may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
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 local regulations covering the transportation of etiologic agents.

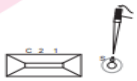
TEST PROCEDURE

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

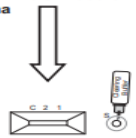
1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.
   - **I) For Whole Blood specimens:** Hold the dropper vertically and **transfer 1 drop or 25 µl of whole blood** to the specimen well (S) of the test device, and then **add 1 drop of buffer** (approximately 35 µL) and start the timer.
   - **ii) For Plasma or Serum:** Use the pipette and add 10µl Serum or Plasma to the specimen well (S) of the test device, and after absorbing the sample then add 1 drop of buffer (approximately 35 µL) and start the timer. See illustration below.

INTERPRETATION OF RESULT

Use Whole Blood/ Serum/ Plasma



1 Drop (25µl) Whole Blood or 10µl Serum/Plasma



Add 1 Drop of clearing Buffer

* Special Instruction *
25µl Whole Blood or 10µl Serum/Plasma and 1 drop clearing Buffer

5 - 20 mins

Negative: One bands appears in Window "C" Region

HIV 1 Positive : Two bands appears in Window "C" and "1" Region

HIV 2 POSITIVE : Two bands appears in Window "C" and "2" Region

HIV 1 & 2 POSITIVE: Three bands appears in Window "C", "2" and "1" Region

INVALID: No bands appears in Window Region. The Result is considered invalid

INVALID: The result should also be considered invalid if only test band (1 & 2) appears and no control band appears in window region.

Wait for the colored line(s) to appear. **Read results at 5-20 minutes. Do not read results after 20 minutes.**

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line 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 a good laboratory practice to confirm the test procedure and to verify proper test performance.

EXPECTED VALUES

The HIV 1 & 2 Rapid Test (Serum/ Plasma/Whole Blood) has been compared with a leading commercial HIV test, demonstrating an overall accuracy greater than or equal to 99.7%.

PERFORMANCE CHARACTERISTICS (Clinical Sensitivity, Specificity and Accuracy)

The HIV 1 & 2 Tri-line Human Immunodeficiency Virus Rapid Test Device (Serum/Plasma/Whole Blood) was evaluated in a multi-center field study, a blood donation center as well as an in-house clinical study. The multi-center study included 1259 specimens & HIV Performance Panel that was purchased from a commercial source. The HIV 1 & 2 Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole blood/Serum/Plasma) was compared to leading commercial ELISA HIV tests. Out of the1259 total specimens, 54 were found positive for HIV 1 and 5 specimens were found Positive For HIV 2 and 1200 Specimens were found negative by ELISA. The MaxLINE HIV 1 & 2 Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole blood/Serum/Plasma) showed 100 % relative sensitivity, and 99.8 % relative specificity compared to ELISA.

MaxLINE HIV 1 & 2 Tri-line Rapid Test Device vs. ELISA

	Observation				
	MaxLINE HIV 1 & 2 Triline		Commercial HIV ELISA		Total Results
Type of Specimen	Positive	Negative	Positive	Negative	
True Positive HIV 1	54	0	54	0	54
True Positive HIV 2	05	0	05	0	05
True Negative HIV1&2	2	1198	0	1200	1200

Relative Sensitivity: 100% Relative Specificity: 99.8 %

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified 100% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, medium positive and a high positive. Three different lots of the HIV 1 & 2 Tri-line Human Immunodeficiency Virus Rapid Test Device (Serum/Plasma/Whole Blood) have been tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified 100% of the time.

INTERFERING SUBSTANCES

The following potentially interfering substances were added to HIV 1 & HIV 2 negative and positive specimens.

Acetaminophen:	20 mg/dL	Caffeine:	20 mg/dL
Acetylsalicylic Acid:	20 mg/dL	Gentisic Acid:	20 mg/dL
Ascorbic Acid:	2g/dL	Albumin:	2 g/dL
Creatin:	200 mg/dL	Hemoglobin	1.1 mg/dL
Bilirubin:	1g/dL	Oxalic Acid:	600mg/dL

None of the substances at the concentration tested interfered in the assay.

LIMITATION

1. The HIV 1 & 2 Tri-line Human Immunodeficiency Virus Rapid Test Device (Serum/Plasma/Whole Blood) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HIV in human serum, plasma or whole blood. Neither the quantitative value nor the rate of increase in HIV antibody concentration can be determined by this qualitative test.
2. The HIV 1 & 2 Tri-line Human Immunodeficiency Virus Rapid Test Device (Serum/Plasma/Whole Blood) will only indicate the presence of antibodies to HIV 1 & HIV 2 in the specimen and should not be used as the sole criteria for the diagnosis of HIV-1 & HIV-2 infection.
3. For confirmation, further analysis of the specimens should be performed, such as ELISA and/or Western Blot analysis.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. This test is intended for screening purposes only. Results should not be used to determine the serotype of HIV infections.
6. Due to possible cross reactivity, the appearance of lines in both 1 and 2 does not necessarily indicate co-infection from HIV-1 & HIV-2 nor can it identify the serotype.

DISCLAIMER:

The manufacturer has take every precaution to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by user error and/or environmental factors. A person who is the subject of the diagnosis should consult a clinician for further confirmation of the result.

WARNING:

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

REFERENCE

1. 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.
2. 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.

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
2	Do Not Reuse		Contains sufficient no. of test

Manufactured in India by :

Healthcare Pvt. Ltd.

Transforming Research into Innovations

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