A Rapid test for Detection of Antibodies to HIV in Human Serum/Plasma.

QUADRO™ HIV 1-2 Ab

Meril Diagnostics

For in vitro diagnostic use
Read this pack insert thoroughly before use

INTENDED USE:

QUADRO™ HIV 1-2 Ab is a Single use, rapid, flow-through *in-vitro* qualitative assay for the detection of antibodies to HIV-1 and HIV-2 in Human Serum, Plasma specimens. The test is intended for used by trained personnel in Medical facility and Clinical laboratory as a screening test for HIV antibody detection.

INTRODUCTION:

Acquired Immunodeficiency Syndrome (AIDS) is caused by two types of Human Immunodeficiency Virus, HIV-1 and HIV-2. Transmission of infection is mainly by exposure to certain infected body fluids e.g., blood and blood products, genital secretion and by transplacental route. Infection by HIV-1 has been reported worldwide, HIV-2 infection has been occurring mainly in West Africa and some European countries. Both these viruses show substantial antigenic cross reactivity in their core proteins, but the envelope glycoproteins are least cross reactive.

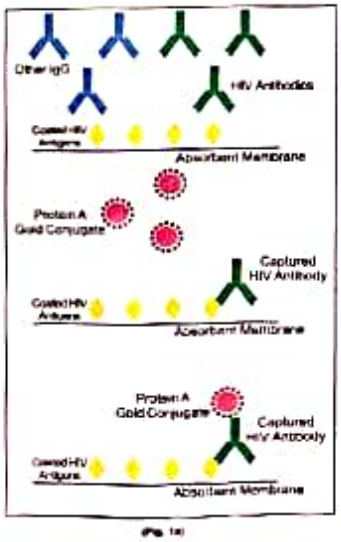
HIV Test kits are classified in terms of generations by WHO as

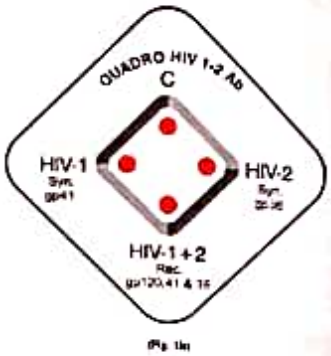
1) 1st Generation Assays: Using Viral Lysate Antigens
2) 2nd Generation Assays: Using Recombinant or Synthetic peptides
3) 3rd Generation Assays: Detects IgM, IgG and IgA antibodies together.
4) 4th Generation Assay: Detects p24 antigen and Antibodies to HIV together.

QUADRO™ HIV 1-2 Ab is designed to detect antibodies to envelope glycoproteins of HIV-1 & HIV-2 by using unique combination of synthetic and recombinant antigens in the same test device differentially. Consequently potential infectious samples of serum and plasma can be identified.

PRINCIPLE:

The QUADRO™ HIV 1 - 2 Ab is a HIV rapid screening test kit contains a nitrocellulose membrane which is pre coated with synthetic peptides of highly immunodominant regions of HIV-1 (gp41) and HIV-2 (gp36) on test region "HIV-1" and "HIV-2" respectively along with a uniquely formulated Recombinant proteins of HIV 1-2 (immunogenic portion of gp120, gp41 & gp36) on the test region of HIV 1-2. As the test sample pass through the membrane, HIV Antibodies if present in the sample reacts with the antigens coated on the membrane at their respective region. Protein A Gold conjugate binds with the Fc region of the ant bodies bound on the membrane and forms a pinkish red colored dot. (Fig. 1a & 1b)





REAGENTS AND MATERIALS PROVIDED:

Each kit contains:

COMPONENTS	DESCRIPTION	PREPARATION
1. QUADRO™ HIV 1-2 Ab Devices	Individual pouch	Cut open the pouch. Bring to R.T before use
2. Assay buffer	Buffer containing chemicals & stabilizers	Bring to R.T before use
3. Gold conjugate	Protein-A colloidal Gold conjugate with stabilizers	Bring to R.T before use
4. Plastic dropper	Plastic dropper for sample addition	Always Ensure to use new dropper

STORAGE AND STABILITY:

The sealed pouches in the test kit to be stored between 2-8°C till the duration of the shelf life as indicated on the pouch. DO NOT FREEZE.

PACK SIZES:

HD4RPD-01 - 10 Test pack
HD4RPD-02 - 25 Test pack
HD4RPD-03 - 50 Test pack
HD4RPD-04 - 100 Test pack

MATERIAL REQUIRED BUT NOT PROVIDED:

Hand Gloves, Syringes, Blood collection tubes, Bio-hazard container, Absorbant cotton balls for blood collection, 0.1% Hypochlorite.

PRECAUTIONS:

1. For in-vitro diagnostics use only
2. Allow all reagents and sample(s) to attain room temperature (18°C to 30°C) before use.
3. Do not use the kit contents beyond the expiry date.
4. Do not touch the nitrocellulose part of the device. Finger print or scratch on nitrocellulose membrane may give erroneous results.
5. Test devices and reagents of different lot must not be mixed and used.
6. Perform the test by using kit's reagents. Performing the test with any other reagents may give erroneous results.
7. Follow the assay procedure and storage instructions strictly. Deviation will lead to erroneous results.
8. Do not use haemolysed or turbid or hazy specimen for testing.
9. Use sufficient volume of sample for testing and add entire 40µl or one drop of the patient sample at once on the reaction membrane.
10. Do not pipette reagents by mouth and do not smoke, eat or drink while handling specimens and performing a test.
11. Do not re-use the Test devices or droppers which lead to aberrant results.

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12. Avoid contact of reagents with eyes and skin.

13. Wear protection clothing such as laboratory coats and disposable gloves and eye protection when specimens are assayed. Avoid re-using gloves or use of washed gloves.

14. Handle sample(s) and used materials as if it is capable of transmitting infection.

15. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. Remnants of sample(s), used materials, pipette tips etc. should be disposed in suitable biohazard container. Materials should be autoclaved at 121°C for 30 minutes or dipped in 0.1% hypochlorite solution for 30 minutes prior to disposal.

16. Clean up spills thoroughly using an appropriate disinfectant.

17. Sodium Azide is present at 0.1% in all assay reagents, which can react with lead and copper plumbing to form highly explosive metal azides. If needed to be discarded into a drain, flush a large amount of water to prevent azide build up.

SPECIMEN COLLECTION AND PREPARATION:

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

PLASMA:

1. Collect blood specimen into a collection tube containing EDTA or Citrate or Heparin.
2. Separate the plasma by centrifugation, 1500 RPM for 10 minutes.
3. Carefully withdraw the plasma into new pre-labelled tube.

SERUM:

1. Collect the blood specimen into a collection tube containing no anticoagulants.
2. Allow the blood to clot.
3. Separate the serum by centrifugation, 1500 RPM for 10 minutes.
4. Carefully withdraw the serum into a new pre-labelled tube. Test the specimens as soon as possible after collection.

Stored separated serum/plasma specimens at 2-8°C up to 3 days can be used for testing. Serum/Plasma specimens should be frozen at -20°C for longer storage. If the sample is frozen, completely thaw the sample prior to testing. Avoid repeated freezing and thawing of specimens.

TEST PROCEDURE:

Bring the specimen and test components to room temperature.

IT IS IMPORTANT TO ENSURE SEQUENTIAL ADDITION OF REAGENTS AS RECOMMENDED AND ALSO ALLOW THE REAGENTS TO SOAK COMPLETELY BEFORE ADDITION OF CONSEQUENT REAGENT.

WHILE ADDITION OF REAGENTS OR SAMPLES ENSURE TO HOLD THE DROPPER OR REAGENTS VERTICALLY ALLOWING FULL DROP OF REAGENT OR SAMPLE FALL OVER DEVICE MEMBRANE EQUALLY. FIG (2)

Fig 2

MIX THE SPECIMEN PROPERLY PRIOR TO ASSAY.

1. When ready to test, open the pouch at the notch and remove device. Place the Test device on a clean, flat surface. Label the patient/sample identity details legibly with a marker.
2. Add 3 drops of Assay buffer onto the untested device and allow it to absorb completely (Fig 3).
3. Add 1 drop or 40 µl of patient serum/plasma with a dropper or micro pipette. Ensure quick and complete addition of the sample at a single instance to allow proper exposure of the sample on the membrane (Fig. 4).
4. Allow the sample to absorb in and add 3 drops of assay buffer onto the membrane to wash any non specific binding over the membrane and allow it to absorb completely (Fig 5).
5. Add 2 drops of Gold Conjugate and allow it to absorb completely. The gold conjugate binds specifically with the Fc portions of the patient antibodies captured on the membrane (Fig 6).
6. Add 3 drops of the assay buffer to allow proper washing of the unbound gold conjugate from the membrane and allow it to absorb completely (Fig 7).

Fig 3

Fig 4

Fig 5

Fig 6

Fig 7

Read the results as per the illustration shown below immediately and discard the tested device as potentially infectious.

INTERPRETATION OF RESULTS:

NEGATIVE RESULT:

If only the Control (C) pinkish red dot is developed, the test indicates that no detectable HIV antibodies are present in the specimen. The result is non-reactive for Anti-HIV (Fig 8).

Fig 8

POSITIVE RESULT:

a) If Control, HIV-1 & HIV-1+2 pinkish red dots are developed, the test indicates for the presence of HIV-1 antibodies in the specimen; the result is reactive for Anti-HIV-1 (Fig. 9).

Fig 9

b) If Control, HIV-2 & HIV 1+2 pinkish red dots are developed, the test indicates for the presence of HIV-2 antibodies in the specimen; the result is reactive for Anti-HIV-2 (Fig. 10).

Fig 10

c) If Control, HIV-1, HIV-2 & HIV 1+2 pinkish red dots are developed, the test indicates for the presence of antibodies to HIV-1 and HIV-2 in the specimen; the result is reactive for Anti-HIV-1 and Anti-HIV-2 simultaneously (Fig. 11).

Fig 11

d) If Control, HIV 1+2 pinkish red dots are developed, the test indicates for the presence of antibodies to either of HIV-1 or HIV-2 and interpret the results after confirming with other supplemental tests (Fig 12).

Fig 12

INVALID RESULT:

If no Control dot is developed, the assay is invalid regardless of color development on 'Test' dots as indicated below. Repeat the assay with a new device (Fig 13).

Fig 13

(In case if the issue persist after repetition, kindly contact our customer service cell at 1800 266 3745)

LIMITATIONS OF THE TEST:

1. This kit is designed for primary screening of HIV infection.
2. As with all diagnostic tests, the test result must always be correlated with clinical findings.
3. A negative result at any time does not preclude the possibility of exposure or infection.
4. Presence of heterophile antibodies in patient's sample with Auto immune disorders, Rheumatic diseases, Renal failure, Kidney dysfunction and autoimmune disorder may lead to false results, need to be reconfirmed with confirmatory tests.
5. A negative result can occur if the quantity of the analyte of interest present in the specimen is below the detection limits of the assay or the analyte of interest that are detected are not present during the stage of disease in which a sample is collected.
6. All the reactive specimens should be tested for reproducibility of their results as per the Regulations followed using the ELISA, CLIA, PCR Test kits approved by the authorities.
7. Repeat the test in case of very faint dot or if have any doubt for test dot.
8. **Use caution while interpreting the results of the test in immunocompromised patients.**
9. HIV-1 & 2 shares their morphology to an extent above 60% and hence certain samples can exhibit cross reactivity between HIV 1 & 2. Appearance of HIV 1 & 2 spots may not be treated as co-infection of HIV 1 & 2 in all conditions and need to confirmed with confirmatory assays for the same.
10. Samples containing particulate matter and Hazy samples can block the membrane resulting in improper flow of reagent and high background colour.
11. **Use caution while interpreting the results of HIV status in Anti retroviral therapy (ART) patients and hyper gammaglobulinemia conditions.**
12. The manufacturer reserves their right to alter and modify the product design specifications without prior information to the buyer.

PERFORMANCE CHARACTERSTICS:

In-house study with a panel of 292 positive and 2652 negative samples whose results were earlier confirmed with commercially approved ELISA & Rapid Test kits was tested with QUADRO™ HIV 1-2 Ab. The results obtained are as follows.

Sensitivity: 100%

Specificity: 99.92%

		QUADRO™ HIV 1-2 Ab Results	
		Positive	Negative
Licenced Test kit results	HIV 1 Reactive (n=270)	270	0
	HIV -2 Reactive (n=20)	20	0
	HIV 1 & 2 Reactive (n=2)	2	0
	HIV Negative samples (n=2652)	2	2650

REPRODUCIBILITY:

Three studies were conducted to evaluate the reproducibility of QUADRO™ HIV 1-2 Ab. For each study a panel of 15 blind coded samples of 5 Reactive and 10 Non reactive samples were tested in triplicate at three different sites using three different lots of QUADRO™ HIV 1-2 Ab.

The overall reproducibility is 100%.

DISPOSAL:

Discard the Test device immediately after reading the results and before discarding it add suitable disinfectant such as 0.1% Hypochlorite on the device membrane and on all other items used for handling the specimen.

Put all items to be disposed in disposable bags and dispose off accordingly.

LIMITED EXPRESSION LIABILITY:

Meril Diagnostics Pvt. Ltd. hereby limits the warranty of the test kits to be used for in vitro Diagnostic assay with in the given limitations mentioned in this manual and its procedures and recommendations suggested are strictly followed. The manufacturer liability is limited to the either replacement of the product or refund of the purchase price of the product and in no case liable to claim any kind of amount greater than the purchase price of the product in respect of damages to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any consequential or economic loss incurred from the product or in its application accordingly.

REFERENCES:

1. Harmening, M.D., Firestone, D., 2005 Modern Blood Banking and Transfusion Practices, 5th ed. USA, FA Davis Company, Philadelphia USA Editor Harmening MN.
2. Chandler, J., Gurmin, T., Robinson, N., 2000. The place of gold in rapid tests. IVD Technology 7(2):37-49.
3. Robinson, N., 2002. Immunogold conjugation for IVD applications. IVD Technology 8(3):33-36.
4. Neogi, U., Bontell, I., Shet, A., Decosta, A., Gupta, S., Diwan, V., Laishram, R.S., Wanchu, A., Ranga, V., Banerjea, A.C., Sonnerborg, A.2012, Molecular epidemiology of HIV-1 subtypes in India: origin and evolutionary history of predominant subtype C. PLOS ONE 7(6): e39819.
5. Granade, T.C., et al., 2010. Rapid detection and differentiation of antibodies to HIV-1 and HIV-2 using multivalent antigens and magnetic immunochromatography testing. Clin Vaccine Immunol. 17(6):1034-1039.
6. HIV Test kits performance characteristics, Report 17, W.H.O Publication Series; http://www.who.int/diagnostics_laboratory/evaluations/hiv/13110 7_hiv_assays17_final.pdf?ua=1: Page No 4

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STANDARD Q® HIV 1/2 Ab Test

SD BIOSENSOR
HEALTHCARE PVT. LTD.

EXPLANATION AND SUMMARY

[Introduction]

AIDS is caused by two known types of HIV (human immunodeficiency virus) , HIV type 1 and HIV type 2. HIV type 1 (HIV-1) is found in patients with AIDS, AIDS-related complex (ARC), and asymptomatic infected individuals at high risk for AIDS. The virus is transmitted by sexual contact, by exposure to infected blood or blood products, or from an infected mother to her fetus or infant. The infection of HIV type 2 (HIV-2) is endemic only in West Africa, and it has been identified in individuals who had sexual relations with individuals from that geographic region. HIV-2 is similar to, but distinct from, HIV-1. Both viruses have similar morphology and lymphotropism, and the modes of transmission appear to be identical. Within the two major HIV types, there is significant variation. HIV-1 has been divided into four groups: group M (for major)-including at least ten subtypes, group O (for outlier), group P, and group N (for non-M, non-O). Similarly, the HIV-2 strains have been classified into at least five subtypes (A through E). STANDARD Q HIV 1/2 Ab Test can detect both HIV-1 antibody and HIV-2 antibody, which first appear significantly later, 20-45 days after infection. Detecting HIV earlier with STANDARD Q HIV 1/2 Ab Test is helpful to prevent future transmission during extremely infectious stage.

[Intended use]

STANDARD Q HIV 1/2 Ab Test is a rapid immunochromatographic 3rd generation test for the detection of antibodies (IgM, IgG & IgA) against HIV 1 & HIV 2 in human serum, plasma or whole blood. The test is for in vitro diagnostic use and is intended as an aid to early diagnosis of HIV infection. This is intended for professional use, only for an initial screening test.

[Test principle]

STANDARD Q HIV 1/2 Ab Test has "T1", "T2" and "C" line pre-coated with recombinant HIV-1 gp41 protein / recombinant HIV-1 subtype O gp41, recombinant HIV-2 gp36 protein and monoclonal anti-chicken IgG respectively. The anti-HIV-1/anti-HIV-1 subtype O in patient sample interacts with the recombinant HIV-1 gp41-gold / recombinant HIV-1 subtype O gp41-gold and the anti-HIV-2 in patient sample interacts with the recombinant HIV-2 gp36-gold in the conjugation pad. The complex of gold conjugated antigens and antibodies moves along the membrane chromatographically to the membrane with assay diluent and is captured by the HIV antigens on the test regions (T1 and T2). If the antibodies against HIV are in the patient sample, visible lines are formed in the test region. The control line should always appear if the test procedure is performed properly.

[Materials Provided]

Components	
Cassette	Specimen transfer device
Buffer Bottle	Instruction for use

KIT STORAGE AND STABILITY

Store the RDT Box at room temperature, 2-40°C / 36-104°F out of direct sunlight. Materials provided are stable until the expiration date printed on the RDT box. Do not freeze.

SPECIMEN COLLECTION AND PREPARATION

[Serum]

1. Collect the whole blood into the commercially available plain tube, NOT containing anti-coagulant such as heparin, EDTA or sodium citrate, by venipuncture and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
2. If serum in the plain tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -20°C / -4°F.
3. It should be brought to room temperature prior to use.

[Plasma]

1. Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin, EDTA or sodium citrate by venipuncture and centrifuge blood to get plasma specimen.
2. If plasma in an anti-coagulant tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -20°C / -4°F.
3. It should be brought to room temperature prior to use.

[Whole Blood]

- **Capillary whole blood**

1. Capillary whole blood should be collected aseptically by fingertip.
2. Clean the area to be lanced with an alcohol swab.
3. Squeeze the end of the fingertip and pierce with a sterile lancet.
4. Collect the capillary whole blood till the marking of the specimen transfer device for testing.
5. The capillary whole blood must be tested immediately after collection.

- **Venous whole blood**

1. Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin, EDTA or sodium citrate by venipuncture.
2. If venous whole blood in an anti-coagulant tube is stored in a refrigerator at 2-8°C/ 36-46°F, the specimen can be used for testing within 1~2 day after collection.
3. Do not use hemolyzed blood specimen.

CAUTION
- Anticoagulants such as heparin or EDTA do not affect the test result.
- As known relevant interference, haemolytic specimen, rheumatoid factors-contained specimen and lipaemic, icteric specimen can lead to impair the test results.
- Use separate disposable materials for each specimen in order to avoid cross-contamination which can cause erroneous results.

TEST PROCEDURE

[Preparation]

1. Carefully read instructions for using the STANDARD Q HIV 1/2 Ab Test.
2. Look at the expiry date at the back of the cassette package. Use another lot, if expiry date has passed.
3. Allow the RDT kit to come at room temperature before opening the cassette package.
4. Open the cassette package & check for the cassette & silica gel.
5. Methods for following steps can be changed depending on the specimen or specimen transfer device.

[Test Procedure]

- **For serum or plasma specimen**

1. Using a micropipette or specimen transfer device collect 10µl (till the marking) of serum or plasma.
2. Add the collected serum or plasma to the specimen well of the cassette.
3. Add 2 drops of buffer into the specimen well of the cassette.
4. Read the test results after 10 minutes. Test can be read up to 20 minutes.

- **For whole blood specimen**

1. Collect 20µl of whole blood by using a micropipette or collect two times 10µl of whole blood till the marking of specimen transfer device.
2. Add the collected whole blood to the specimen well of the cassette.
3. Add 2 drops of buffer into the specimen well of the cassette.
4. Read the test results after 10 minutes. Test can be read up to 20 minutes.

CAUTION
- Do not read test results after 20 minutes. It may give false results.

INTERPRETATION OF TEST RESULTS

Non-Reactive

The presence of only control line (C) within the result window indicates that the specimen is non-reactive for antibodies to HIV-1 and/or HIV-2.

Reactive

1) The presence of two lines as control line (C) and test line (1) within the result window indicates that the specimen is reactive for antibodies to HIV-1.
2) The presence of two lines as control line (C) and test line (2) within the result window indicates that the specimen is reactive for antibodies to HIV-2.
3) The presence of three lines as control line (C) , test line (1) and test line (2) within the result window indicates that the specimen is reactive for antibodies to HIV-1 and HIV-2.

Invalid

If the control band ("C" Control line) is not visible within the result window, the result is considered Invalid. The directions may not have been followed correctly. In such case, it is recommended to retest the specimen with a new cassette.

CAUTION
- There is an homology in the amino acid sequence between HIV-1 and HIV-2 due to which they have a cross reactivity of 30-70%. Hence, appearance of test lines for both HIV-1 and HIV-2 antibodies on the cassette does not necessarily imply co-infection from HIV-1 & HIV-2. To determine the virus type or diagnose a co-infection accurately, a confirmatory test such as Western Blot or PCR must be performed.

LIMITATION OF TEST

1. The test should be used for the detection of antibodies to HIV in human serum, plasma or whole blood specimen.
2. Neither the quantitative value nor the rate of antibodies to HIV concentration can be determined by this qualitative test.
3. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
4. A non-reactive test result may occur if the level of extracted antibody in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained.
5. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
6. The test result must always be evaluated with other data available to the physician.

QUALITY CONTROL

[Internal Quality Control]

STANDARD Q HIV 1/2 Ab Kit has test line and control line on the surface of each cassette. All the test lines and control line in result window are not visible before applying specimen. The control line is used for procedural control. It will appear if the test has been performed correctly and the reagents are functional. If it does not appear, the test results are not valid and the test must be repeated. In addition, good laboratory practice recommends the daily use of control materials to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERISTICS

As per the evaluation conducted at different sites in India, the performance characteristics of STANDARD Q HIV 1/2 Ab is found to be:

Sensitivity - 100% | **Specificity - 99.49%**

WARNINGS AND PRECAUTIONS

1. Do not re-use the kit.
2. Do not use the kit if the cassette package is damaged or the seal is broken.
3. Do not use the buffer bottle of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Handle all specimens as if they contain infectious agents.
8. Observe established precautions against microbiological hazards throughout testing procedures.
9. Dispose off all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and bio-hazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
10. Silica gel in cassette packaging is to absorb moisture and prevent humidity from affecting products.
11. Buffer contain sodium azide as a preservative. If these materials are to be disposed off through sink or other common plumbing system, flush with generous water to prevent accumulation of potentially explosive compound.
12. For in vitro diagnostic use only.
13. Do not use the kit contents beyond the expiry date printed outside the box.
14. Immediately perform the test after removing the test device from the cassette package.
15. Discard the cassette immediately after reading result.

BIBLIOGRAPHY

1. Owen SM et al. Alternative Algorithms for Human Immunodeficiency Virus Infection Diagnosis Using Tests That Are Licensed in the United States. J Clin Microbiol 46:1588-1595, 2008.
2. Barre-Sinoussi F, Chermann JC, Rey F, et al. Isolation of a T-lymphotropic retrovirus from a patient at risk for acquired immune deficiency syndrome (AIDS). Science 220:868-871, 1983.
3. Centers for Disease Control. Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. Morbidity and Mortality Weekly Rep 37:377-388, 1988.
4. Hoff R, Weibin BJ, Schwerdel M, et al. Specific antibodies to HIV-2 detected in an anonymous newborn blood specimen from Massachusetts. Fourth Consensus Conference on Testing for Human Retroviruses, March 1989.
5. Charneau P, Borman AM, Quillant C, et al. Isolation and envelope sequence of a highly divergent.

Product Disclaimer

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the SD BIOSENSOR HEALTHCARE PVT. LTD. and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning

The SD BIOSENSOR HEALTHCARE PVT. LTD. and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether reactive or non reactive, in the use of this product.

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Any inquiries regarding the instruction provided should be addressed to: care@sdbiosensor.co.in or call at - **1800-10-23105**
www.sdbiosensor.co.in

CAT Catalogue number | IVD In vitro Diagnostics | Consult instructions for use | Contains Sufficient for <xx> Tests | Caution | To indicate the temperature limitations in which the transport package has to be kept and handled | Do not re-use | Use by | LOT Batch code | Manufacturer | Date of manufacture | Indicate that you should keep the product dry | Keep away from sunlight | Do not use if packaging is damaged | This way up