HIV 1+2 Test Strip (2–30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADHIV1	50 Tests

Intended Use:
The HIV 1/2 Rapid Test Strip (Whole Blood /Serum/Plasma) is a rapid visual immunoassay for the qualitative, presumptive detection of antibodies to HIV-1/HIV-2 in human Whole Blood, serum or plasma specimens. This kit is intended for use as an aid in the diagnosis of HIV infection.

Summary:
HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virion is surrounded by a lipid envelope that is derived from 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-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals. Both HIV-1 and HIV-2 elicit immune response. Detection of HIV antibodies in serum, plasma or whole blood 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. Despite differences in their biological characters, serological activities and genome sequences, HIV-1 and HIV-2 show strong antigenic cross-reactivity. Most HIV-2 positive sera can be identified by using HIV-1 based serological tests.

Test Principle:
The HIV 1/2 Rapid Test Strip (Whole Blood/Serum/Plasma) detects antibodies to HIV-1/HIV-2 through visual interpretation of colour development on the internal strip. Recombinant HIV antigens are immobilized on the test region of the membrane. During testing, the specimen reacts with HIV antigen conjugated to coloured particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there are sufficient HIV-1/HIV-2 antibodies in the specimen, a coloured band will form at the test region of the membrane. The presence of this coloured band indicates a positive result, while its absence indicates a negative result. The appearance of a coloured band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

Materials Provided
Individually pouched test strips
Disposable pipettes
Buffer
Package Insert

Materials not provided: Timer, Specimen collection container, Centrifuge

Precautions:

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

Reagent Preparation and Stability:

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

Specimen Collection and Storage:

- The HIV 1/2 Rapid Test Strip (Whole Blood/Serum/Plasma) is intended for use with human Whole Blood, serum or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave 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.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.

Assay Procedure:

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. For best results, the assay should be performed within one hour.
2. Using the provided disposable pipette, transfer 2 drops of serum/plasma (approximately 50 µL) to the sample pad of the Strip with the provided disposable pipette, then add 1 drop of buffer and start the timer.
   OR
   Transfer 2 drop of whole blood specimen (approximately 50 µL) to the sample pad of the Strip with the provided disposable pipette, then add 1 drop of buffer and start the timer.
   OR
   Allow 2 hanging drops of fingerstick whole blood specimen to fall into the sample pad on the Strip, then add 1 drop of buffer and start the timer.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
   As the test begins to work, colour will migrate across the membrane.
3. Wait for the coloured band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

Interpretation of Results:

POSITIVE: Two coloured bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one coloured band appears, in the control region (C). No apparent coloured band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of colour in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of colour in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

Quality Controls:

- Internal procedural controls are included in the test. A coloured band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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 of the Test:

1. The HIV 1/2 Rapid Test Strip (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should be only used for the qualitative detection of antibodies to HIV-1/HIV-2.
2. The HIV 1/2 Rapid Test Strip (Whole Blood/Serum/Plasma) will only indicate the presence of HIV-1/HIV-2 antibodies in the specimen and should not be used as the sole criteria for the diagnosis of HIV viral infection.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the presence of HIV-1/HIV-2 antibodies in blood, as antibodies may be present below the minimum detection level of the test.
4. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Performance Characteristics:

Table: HIV 1/2 Rapid Test vs. EIA

Relative Sensitivity:
>99.9% (99.5%-100.0%)*
Relative Specificity:
99.9% (99.6%-99.9%)*
Overall Agreement:
>99.9% (99.7%-99.9%)*

***95% Confidence Interval**

		HIV 1/2 Rapid Test +	HIV 1/2 Rapid Test -	Total
EIA	+	722	0	722
	-	2	1956	1958
		724	1956	2680

References:

Prestige Diagnostics U.K. Ltd 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 2564 2100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk

V2: rev Sep 2014

1. Chang SY, Bowman BH, Weiss JB, Garcia RE, White TJ. The origin of HIV-1 isolate HTLV-IIIB. Nature. 1993 Jun 3; 363(6428): 466-9.
2. Arya SK, Beaver B, Jagodzinski L, Ensoli B, Kanki PJ, Albert J, Fenyo EM, Biberfeld G, Zagury JF, Laure F, et al. New human and simian HIV-related retroviruses possess functional transactivator (tat) gene. Nature. 1987 Aug 6-12;328(6130):548-50.
3. Caetano JA. [Immunologic aspects of HIV infection]. Acta Med Port. 1991 Dec; 4 Suppl 1: 52S-58S.
4. Janssen RS, Satten GA, Stramer SL, Rawal BD, O'Brien TR, Weiblen BJ, Hecht FM, Jack N, Cleghorn FR, Kahn JO, Chesney MA, Busch MP. New testing strategy to detect early HIV-1 infection for use in incidence estimates and for clinical and prevention purposes. JAMA. 1998 Jul 1; 280(1): 42-8.
5. Travers K, Mboup S, Marlink R, Guèye-Nidaye A, Siby T, Thior I, Traore I, Dieng-Sarr A, Sankalé JL, Mullins C, et al. Natural protection against HIV-1 infection provided by HIV-2. Science. 1995 Jun 16; 268(5217): 1612-5.
6. Greenberg AE, Wiktor SZ, DeCock KM, Smith P, Jaffe HW, Dondero TJ Jr. HIV-2 and natural protection against HIV-1 infection. Science. 1996 Jun 28; 272(5270): 1959-60

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer	2	Do not reuse

Prestige Diagnostics U.K. Ltd 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 2564 2100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk

V2: rev Sep 2014