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 chromatographic immunoassay for the qualitative 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 the 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.
The HIV 1+2 Rapid Test Strip (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HIV 1 and/or HIV 2 in whole blood, serum or plasma specimen. The test utilizes latex conjugate and multiple recombinant HIV proteins to selectively detect antibodies to the HIV 1+2 in whole blood, serum or plasma.

Test Principle:
The HIV 1+2 Rapid Test Strip (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibodies to HIV 1+2 in whole blood, serum or plasma. The strip is pre-coated with recombinant HIV antigens. During testing, the whole blood, serum or plasma specimen reacts with HIV antigen coated particles in the test strip. The mixture then migrates upward to the test line region. If the specimen contains antibodies to HIV 1 and/or HIV 2, a coloured line will appear in the test line region, indicating a positive result. If the specimen does not contain HIV 1 and/or HIV 2 antibodies, no coloured line will develop in the test line region, indicating a negative result. To serve as a procedural control, a coloured line should always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Reagents:
The test contains HIV 1+2 recombinant antigen coated particles and HIV 1+2 recombinant antigens coated on the membrane.

Materials Provided
Individually pouched test strips
Disposable pipettes
Buffer
Instructions for Use sheet

Materials not provided: Timer, specimen collection container, lancet (for fingerstick whole blood only), Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only), centrifuge

Precautions:

- For professional *in vitro* diagnostic use only. Do not use after expiry date.
- Do not eat, drink or smoke in the area where the specimens or test strip are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing including laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

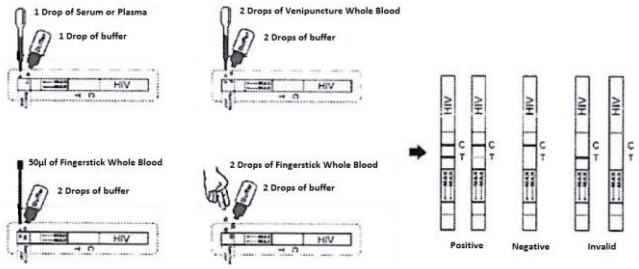
Reagent Storage and Stability:
Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable until the expiry date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use after the expiry date.

Specimen Collection and Preparation:

- The HIV 1+2 Rapid Test Strip (Whole Blood/Serum/Plasma) can be performed using whole blood (from venepuncture or fingerstick), serum or plasma.
- 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 sterile lancet. 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 by using a capillary tube:
    - Touch the end of the capillary tube to the blood until filled to approximately 50µl. Avoid air bubbles
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test strip.
  - Add the Fingerstick Whole Blood specimen to the test by using hanging drops:
    - Position the patient's finger so that the drop of blood is just above the specimen area of the test strip.
    - Allow 2 hanging drops of fingerstick whole blood to fall into the centre of the specimen area on the test strip, or move the patient's finger so that the hanging drop touches the centre of the specimen area. Avoid touching the finger directly to the specimen area.
- Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear non-haemolysed specimens.
- Testing should be performed soon after the specimens have been collected. 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 stored below -20°C. Whole blood collected by venepuncture 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 must be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freeze/thaw cycles.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

Assay Procedure:

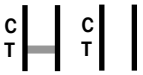
Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.
1. Remove the Test Strip from its sealed pouch and perform the test within one hour. Lay the test cards on a clean level surface.
2. For Serum or Plasma specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25 µl) to the specimen area, 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 whole blood (approximately 50 µl) to the specimen area, then add 2 drops of buffer (approximately 80 µl), and start the timer. See illustration below.
For Fingerstick Whole Blood specimens:
3. To use a capillary tube: Fill the capillary tube and transfer approximately 50µl of fingerstick whole blood specimen to the specimen area of test strip, then add 2 drops of buffer (approximately 80µl) and start the timer. See illustration below.
4. Wait for the coloured line(s) to appear. Read results 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).
Note: The intensity of the colour in the test line region (T) will vary depending on the concentration of HIV antibodies present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive.

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.

Quality Controls:
A procedural control is included in the test. A coloured 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 test strip; however, it is recommended that positive and negative control be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

	Manufacturer		Do not reuse

Limitations of the Test:

1. The HIV 1+2 Rapid Test Strip (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of HIV antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in HIV antibodies can be determined by this qualitative test.
2. The HIV 1+2 Rapid Test Strip (Whole Blood/Serum/Plasma) will only indicate the presence of HIV antibodies in the specimen and should not be used as the sole criteria for the diagnosis of HIV infection.
3. Clinical diagnosis cannot be made on the results obtained using the HIV 1+2 Rapid Test Strip alone but must be determined in conjunction with other clinical information available to the physician.
4. 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 preclude the possibility of HIV infection.

Expected Values

The HIV 1+2 Rapid Test Strip (Whole Blood/Serum/Plasma) has been compared with a licenced HIV EIA test. The correlation between these two systems is 99.9%.

Performance Characteristics:

Sensitivity and Specificity

The HIV 1+2 Rapid Test Strip (Whole Blood/Serum/Plasma) has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial ELISA HIV test using clinical specimens. The results show that the relative sensitivity of the HIV 1+2 Rapid Test Strip (Whole Blood/Serum/Plasma) is >99.9% and the relative specificity is 99.9%

Method		ELISA		Total Result
HIV 1+2 Rapid Test Strip (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	108	1	109
	Negative	0	925	925
Total Result		108	926	1034

Relative Sensitivity: >99.9% (95%CI*:97.3%~100%)
Relative Specificity: 99.9% (95% CI*:99.4%~100%)
Accuracy: 99.9% (95%CI*: 99.5%~100%)
*Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative and positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the HIV 1+2 Rapid Test Strip (Whole Blood/Serum/Plasma) were tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The HIV 1+2 Rapid Test Strip (Whole Blood/Serum/Plasma) has been tested by HAMA, RF, HBsAg, HBsAb, HBeAb, HBcAb, HCV, Syphilis, H.Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

Interfering Substances

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

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

None of the substances interfered in the test at the concentration listed.

References:

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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.
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REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by

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