HIV 4th GEN AG AB DEVICE (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADHIV3	20 Tests

Intended Use:
The HIV Ag/Ab 4th Gen. Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of HIV type 1 antibody, type 2 antibody and HIV 1 P24 antigen in whole blood, serum or plasma specimen to aid in the diagnosis of HIV infection.

Summary:
• **HIV 1+2**
HIV (Human Immunodeficiency Virus) 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.1 HIV-1 consists of Subtype M and Subtype O. Highly divergent strains of HIV-1 were first recognized in 1990 and grouped provisionally as Subtype O as this variation has similar glycoprotein markers to HIV-1 but a slight variation to the protein marker. Although rarely compared to HIV-1 and HIV-2, infections caused by Subtype O have so far been identified in Africa (Cameroon), France and Germany. HIV-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals.2 HIV-1, HIV-2, and Subtype O all elicit immune responses.3 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.4 Despite the differences in their biological characters, serological activities and genome sequences, HIV-1, HIV-2, and Subtype O show strong antigenic cross-reactivity.5,6 Most HIV-2 positive sera can be identified by using HIV-1 based serological tests.
The HIV Ag/Ab 4th Gen. Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibodies to HIV type 1 and type 2 in whole blood, serum or plasma specimen.
• **HIV p24**
The HIV p24 antigen is a small piece of protein that is found on the capsule of the HIV virus. When a person is infected with HIV, these bits of protein can be found floating in the blood. The HIV p24 antigen rapid test is the test that detects these bits of protein. This test was first developed as a HIV screening test but rapidly ran out of favour due to the development of more advanced NAAT tests. The window period for p24 testing is also very small. This test alone is only accurate for between 3 and 6 weeks post exposure. So it is a test with very limited applications unless combined with HIV p24 antigen test. The presence of p24 antigen in the blood indicated a recent HIV infection.
The HIV p24 Antigen Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of p24 antigen to HIV 1 in whole blood, serum or plasma specimen. The test utilizes latex conjugate HIV p24 antibody to selectively detect p24 antigen to the HIV type 1 in whole blood, serum or plasma.

Test Principle:
• HIV 1.2
The HIV 1.2 Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibodies to HIV-1, HIV-2, and Subtype O in whole blood, serum or plasma. The membrane is pre-coated with recombinant HIV antigens in the test line regions, T1 and T2. The T1 test line is pre-coated with HIV-1 and Subtype O antigen and the T2 test line is pre-coated with HIV-2 antigen. During testing, the whole blood, serum or plasma specimen reacts with HIV antigen coated 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 and/or Subtype O, or HIV-2, one coloured line will appear in the test line region; if the specimen contains antibodies to HIV-1 and/or Subtype O, and HIV-2, two coloured lines will appear in the test line region. Both indicate a positive result. If the specimen does not contain HIV-1, Subtype O, and/or HIV-2 antibodies, no coloured line will appear in the test line region indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.
• HIV p24
The HIV p24 Antigen Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of p24 antigen to HIV type 1 in whole blood, serum or plasma. The membrane is pre-coated with mouse anti-HIV p24 antibody. During testing, the whole blood, serum or plasma specimen reacts with HIV p24 antibody coated particles in the test device. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with HIV p24 antibody on the membrane in the test line region. If the specimen contains p24 antigen to HIV type 1, a coloured line will appear in the test line region, indicating a positive result. If the specimen does not contain p24 antigen to HIV type 1, a coloured line will not appear in the test line region, indicating a negative result. To serve as a procedural control, a coloured line will 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 type 1 and tpe2 antigen, HIV p24 antibody coated particles and HIV type1 recombine antigen, type 2 recombine antigen, and p24 antibody coated on the membrane.

Materials Provided
Test Device
Droppers
Buffer
Package Insert

Materials not provided: Specimen collection containers, Timer, Lancets (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 expiration date.
• Do not eat, drink or smoke in the area where the specimens or test device 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 such as 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.

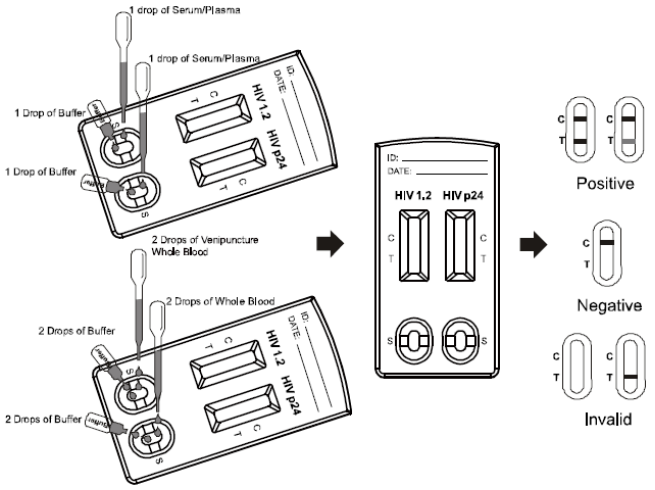
Storage and Stability:
Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use after the expiration date.

Specimen Collection and Preparation:
• The HIV 4th Gen Ag Ab Test Device (Whole Blood/Serum/Plasma) can be performed using Whole blood (from venipuncture or fingerstick), serum or plasma specimen.
• 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 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 to the specimen area of the test device.
• 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 device.
  • Allow 2 hanging drops of fingerstick whole blood to fall into the centre of the specimen area on the test device, 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 hemolysis. Use only clear non-hemolyzed specimens.
• Testing should be performed immediately 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 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.
• 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.
• If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

Assay Procedure:
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the device on a clean and level surface.
For **Serum or Plasma** specimen: 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** specimen: 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 80µL), and start the timer. See illustration below.
For **Fingerstick Whole Blood** specimen:
- To use a capillary tube: Fill the capillary tube **and transfer approximately 50 µL of fingerstick whole blood specimen** to the specimen area of test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer. See illustration below.
- To use hanging drops: Allow **2 hanging drops of fingerstick whole blood specimen** (approximately 50 µL) to fall into the specimen area of test device,

then **add 2 drops of buffer** (approximately 80 µL) and start the timer. See illustration below.

3. 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 lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).

***NOTE:** The intensity of the colour in the test line region (T) will vary depending on the concentration of HIV type 1 antibody, type 2 antibody or HIV typ1 P24 antigen present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive.

NEGATIVE: One coloured line appears in the control line region (C). No line appears in the test line 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. If the problem persists, discontinue using the test device 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 device; 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 of the Test:

1. The HIV 4th Gen. Ag Ab Test Device (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of HIV type 1 antibody, HIV type 2 antibody and HIV type 1 P24 antigen in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in HIV type 1 antibody, HIV type 2 antibody and HIV type 1 P24 antigen can be determined by this qualitative test.
2. The HIV 4th Gen. Ag Ab Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of HIV type 1 antibody, HIV type 2 antibody and HIV type 1 P24 antigen in the specimen and should not be used as the sole criteria for the diagnosis of HIV infection.
3. As with all rapid test devices, all results must be interpreted together 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 4th Gen. Ag Ab Test Device (Whole Blood/Serum/Plasma) has been compared with a leading commercial HIV EIA test. The correlation between these two systems is over 97%.

Performance Characteristics:

Sensitivity and Specificity

- **HIV 1+2**

The HIV 1+2 Test Device (Whole Blood/Serum/Plasma) has correctly identified specimens of 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 Device (Whole Blood/Serum/Plasma) is >99.9% and the relative specificity is 99.9%.

Method		ELISA		Total Result
HIV 1+2 Test Device (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%);
Relatively Specificity: 99.9% (95%CI*: 99.4%-100%);
Accuracy: 99.9% (95%CI*: 99.5%-100%). *Confidence Intervals

- **HIV p24**

The HIV p24 Test Device (Whole Blood/Serum/Plasma) has been compared to a leading commercial ELISA HIV test using clinical specimens. The results show that the relative sensitivity of the HIV p24 Antigen Rapid Test Device (Whole Blood/Serum/Plasma) is 80% and the relative specificity is 97.6%.

Method		ELISA		Total Result
HIV p24 Test Device (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	24	2	26
	Negative	6	298	304
Total Result		30	300	330

Relative sensitivity: 80% (95%CI*: 61.4%~92.3%);
Relative specificity: 99.3% (95%CI*: 97.6%~99.9%);
Accuracy: 97.6% (95%CI*: 95.3%~98.9%). *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, low positive, medium positive and high 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 4th Gen. Ag Ab Test Device (Whole Blood/Serum/Plasma) have been tested over a 10-days period using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The HIV 4th Gen. Ag Ab Test Device (Whole Blood/Serum/Plasma)has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, 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: 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.

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

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