HIV p24 Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF IHIG-402	English

A rapid test for the diagnosis of Human Immunodeficiency Virus to detect p24 antigen to HIV type 1 qualitatively in Whole Blood,Serum or plasma.
For professional in vitro diagnostic use only.

【INTENDED USE】

The HIV p24 Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of p24 antigen to Human Immunodeficiency Virus(HIV) type 1 in whole blood, serum or plasma to aid in the diagnosis of HIV infection.

【SUMMARY】

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 favor 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 Cassette (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.

【PRINCIPLE】

The HIV p24 Antigen Rapid Test Cassette (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 Cassette. 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 colored 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 colored line will not 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.

【REAGENTS】

The test contains HIV type 1 p24 antibody coated particles and mouse anti-HIV p24 antibody coated on the membrane.

【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 Cassettes 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 p24 Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using Whole blood(from venipuncture 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 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 Cassette.
  - 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 Cassette.
    - Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test Cassette, or move the patient's finger so that the hanging drop touches the center 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 fingersticks 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.

【MATERIALS】

Materials provided

- Test Cassettes
- Buffer
- Droppers
- Package insert

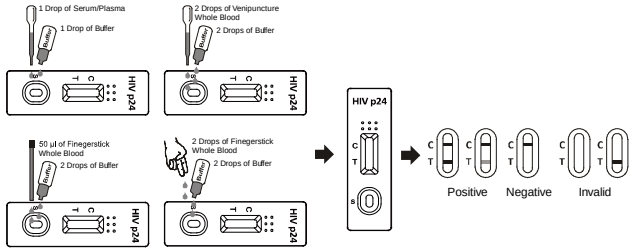
Materials required but not provided

- Specimen collection containers
- Timer
- Centrifuge

【DIRECTIONS FOR USE】

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 Cassette from the sealed pouch and use it as soon as possible.
2. Place the Cassette 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 Cassette, 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 Cassette, then **add 2 drop of buffer** (approximately 80 μL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after **20 minutes**.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of HIV p24 antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored 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 Cassette immediately and contact your local distributor.

【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 test Cassette; 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】

1. The HIV p24 Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of HIV p24 antigen in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in HIV p24 antigen can be determined by this qualitative test.
2. The HIV p24 Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of p24 antigen to HIV type 1 in the specimen and should not be used as the sole criteria for the diagnosis of HIV infection.
3. As with all diagnostic tests, 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 p24 Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial HIV EIA test. The correlation between these two systems is 99.1%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The HIV p24 Antigen Rapid Test Cassette (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 Cassette (Whole Blood/Serum/Plasma) is 96.7% and the relative specificity is 99.3%.

Method		ELISA		Total Result
HIV p24 Antigen Rapid Test Cassette(Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	29	2	31
	Negative	1	298	299
Total Result		30	300	330

Relative sensitivity: 96.7% (95%CI*: 82.8%~99.9%);
Relative specificity: 99.3% (95%CI*: 97.6%~99.9%);
Accuracy: 99.1% (95%CI*: 97.4%~99.8%). *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 p24 Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested over a 3-day period using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The HIV p24 Rapid Test Cassette (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.

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit		Do not reuse
IVD	For in vitro diagnostic use only		Use by	REF	Catalog #
2°C 30°C	Store between 2-30°C	LOT	Lot Number		

Hangzhou AllTest Biotech Co., Ltd.
#550, Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou - 310018, P. R. China
www.alltests.com.cn

Number: 145311200
Effective date: 2016-06-28