HIV 1.2 and P24 Combo Rapid Test Cassette (Whole Blood/Serum/Plasma)

Package Insert

A rapid test for the diagnosis of Human Immunodeficiency Virus (HIV) type 1 antibody, type 2 antibody and type 1 p24 antigen qualitatively in Whole Blood, Serum or Plasma specimen.

For professional in vitro diagnostic use only.

【INTENDED USE】

The HIV 1.2 and P24 Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of HIV type 1 antibody, type 2 antibody and type 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 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 2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals.[2] Both HIV 1 and HIV 2 elicit immune response.[3] Detection of HIV antibodies in whole blood, serum or plasma 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 characteristics, serological activities and genome sequences, HIV 1 and HIV 2 show strong antigenic cross-reactivity.[5,6] Most HIV 2 positive sera can be identified by using HIV 1 based serological tests.

The HIV 1.2 Rapid Test (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibodies to HIV type1 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 favor due to the development of more advanced NAT tests.[7]The window period for p24antigen testing is also very small. This test alone is only accurate for between 3 and 6 weeks post exposure.[8]So it is a test with very limited applications unless combined with HIV antibody test. The presence of p24 antigen in the blood indicated a recent HIV infection.[9]

The HIV p24 Antigen Rapid Test (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 】

- **HIV 1.2**

The HIV 1.2 Rapid Test (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 membrane is pre-coated with recombinant HIV antigens. During testing, the whole blood, serum or plasma specimen reacts with HIV antigens coated particles in the test Cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with recombinant HIV antigens on the membrane in the test line region. If the specimen contains antibodies to HIV 1 and/or HIV 2, a colored 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, 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.

- **HIV p24**

The HIV p24 Antigen Rapid Test (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 and type 2 antigen, HIV p24 antibody coated particles and HIV type1 recombine antigen, type 2 recombine antigen, and 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 1.2 and P24 Combo Rapid Test Cassette (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 Cassette.
- 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.
- EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the coagulant tube for collecting the blood specimen.

【MATERIALS】

Materials provided

•Test Cassettes •Droppers • Buffer • Package insert

Materials required but not provided

• Specimen collection containers • Timer • Centrifuge
• Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
• Lancets (for fingerstick whole blood only)

【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.

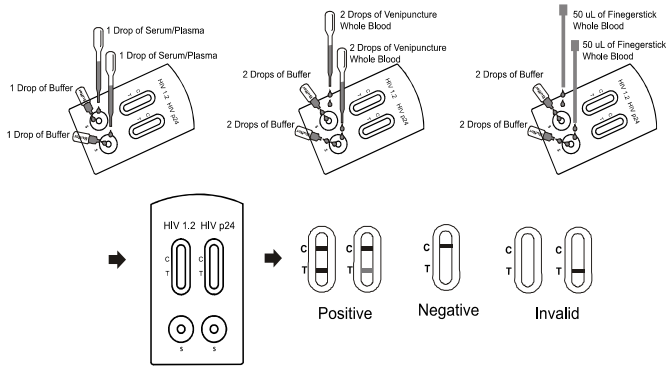
   For **Serum or Plasma** specimen: Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 μL) to the specimen area of test Cassette, then **add 1 drop of buffer** (approximately 40 μL),and start the timer, see illustration below.

   For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 μL) to the specimen area of test Cassette, 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.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the results after **20 minutes**.

Note: It is suggested not to use the buffer, beyond 30 days after opening the vial.



【INTERPRETATION OF RESULTS】

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 type 1 antibody, type 2 antibody or HIV type1 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 quality 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 1.2 and P24 Combo Rapid Test Cassette (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. 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 1.2 and P24 Combo Rapid Test Cassette (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 cassettes, 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.
5. The hematocrit of the whole blood should be between 25% and 65%.

【EXPECTED VALUES】

The HIV 1.2 and P24 Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial HIV ELISA test. The correlation between these two systems is over 97%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

- **HIV 1.2**

The HIV 1.2 Rapid Test Cassette (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 Cassette (Whole Blood/Serum/Plasma) is >99.9% and the relative specificity is 99.9%.

Method		ELISA		Total Results
HIV 1.2 Rapid Test cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	108	1	109
	Negative	0	925	925
Total Results		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 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 80.0% and the relative specificity is 99.3%.

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

Relative sensitivity: 80.0% (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 1.2 and P24 Combo Rapid Test Cassette(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 1.2 andP24 Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by anti-HAMA IgG, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-HCV IgG, anti-Syphilis IgG, anti-RF IgG, anti-MONO IgM, anti-H. Pylori IgG, anti-Rubella IgG, anti-Rubella IgM, anti-CMV IgG, anti-CMV IgM, anti-Toxo IgG, anti-Toxo IgM, 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 g/dL
Bilirubin: 1g/dL	Oxalic Acid: 600mg/dL

None of the substances at the concentration tested interfered in the assay.

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Number: 145402502
Effective date: 2017-10-24