

HIV 1.2 and Syphilis Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

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A rapid test for the qualitative detection of antibodies to HIV type 1, type 2 and syphilis antibodies (IgG and IgM) to *Treponema pallidum* (TP) in whole blood, serum or plasma.
For professional *in vitro* diagnostic use only.

【INTENDED USE】

The HIV1.2 and Syphilis Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to HIV type 1, type 2 and syphilis-antibodies (IgG and IgM) to *Treponema Pallidum* (TP) in whole blood, serum or plasma.

【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 virion 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, 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.

Treponema pallidum (TP) is the causative agent of the venereal disease Syphilis. TP is a spirochete with an outer envelope and a cytoplasmic membrane.⁷ Relatively little is known about the organism in comparison with other bacterial pathogens. According to the Center for Disease Control (CDC), the number of cases of Syphilis infection has markedly increased since 1985.⁸ Some key factors that have contributed to this rise include the crack cocaine epidemic and the high incidence of prostitution among drug users.⁹ One study reported a substantial epidemiological correlation between the acquisition and transmission of the HIV virus and Syphilis.¹⁰

Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of Syphilis. Primary Syphilis is defined by the presence of a chancre at the site of inoculation. The antibodies response to the TP bacterium can be detected within 4 to 7 days after the chancre appears. The infection remains detectable until the patient receives adequate treatment.¹¹

【PRINCIPLE】

The HIV 1.2 and Syphilis Combo Rapid Test (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibodies to HIV 1.2 and TP antibodies (IgG and IgM) in whole blood, serum or plasma. The membrane is pre-coated with recombinant HIV antigens and Syphilis antigens. During testing, the whole blood, serum or plasma specimen reacts with HIV antigen and/or Syphilis antigen coated particles in the test. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with recombinant HIV antigen and/or Syphilis antigen on the membrane and generates a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test cassette contains HIV1.2 recombinant antigens and Syphilis antigen conjugated particles, HIV1.2 recombinant antigens and Syphilis antigen coated on one membrane.

【PRECAUTIONS】

● For professional *in vitro* diagnostic use only. Do not use after the expiration date.

● Do not eat, drink or smoke in the area where the specimens or test Cassettes are handled.

● Do not use test kit pouch 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】

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

● The HIV 1.2 and Syphilis Combo 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 pad. 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 well 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 Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

【MATERIALS】

Materials provided

- Test cassettes
- Droppers
- Buffer
- Package insert

Materials required but not provided

- Specimen collection containers
- Centrifuge (for plasma only)
- Sterile Lancets(for Fingerstick Whole Blood only)
- Timer
- Capillary tubes(for Fingerstick Whole Blood only)

【DIRECTIONS FOR USE】

Allow test cassette, specimen, buffer and/or controls to equilibrate to 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. Best results will be obtained if the assay is performed within one hour.

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 well, then **add 1 drop of buffer** (approximately 40 µL), and start the timer, see illustration below.

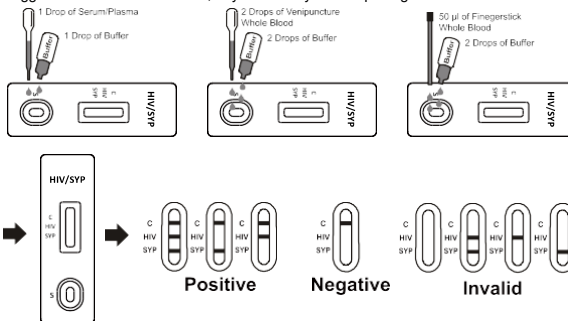
For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen well, then **add 2 drops of buffer** (approximately 80 µL), and start the timer. See illustration below.

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 well 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 result after 20 minutes.

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



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above.)

HIV1.2 POSITIVE:* Two lines appear. One line should be in the control line region (C) and another apparent line should be in the HIV line region.

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

HIV1.2 and Syphilis POSITIVE:*Three lines appear. One line should be in the control line region (C) and two lines appear in the HIV and SYP regions.

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of HIV1.2 and/or Syphilis present in the specimen. Therefore, any shade of color in the HIV1.2 and/or Syphilis region should be considered positive.

NEGATIVE: One line appears in the control line region (C). No line appears in the HIV and SYP region.

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 kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal quality procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; 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 Syphilis 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 antibodies and/or Syphilis 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 and Syphilis Combo Rapid Test Cassette will only indicate the presence of HIV antibodies and Syphilis antibodies in the specimen and should not be used as the sole criteria for the diagnosis of HIV and/or TP 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 and/or TP infection.

5. The hematocrit of the whole blood should be between 25% and 65%.

【EXPECTED VALUES】

The HIV 1.2 and Syphilis Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with leading commercial ELISA tests for HIV and TPPA tests for syphilis respectively, demonstrating an overall accuracy >99%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

1. HIV 1.2 result	Method	ELISA		Total Results
		Positive	Negative	
HIV1.2 and Syphilis Combo Rapid Test for HIV 1.2	Results			
	Positive	140	1	141
	Negative	0	459	459
Total Result		140	460	600

Relative Sensitivity: >99.9% (95%CI*: 97.9%-100%)

*Confidence Intervals

Relative Specificity: 99.8% (95%CI*: 98.9%-100%);

Accuracy: 99.8% (95%CI*: 99.1%-100%).

2. Syphilis result

HIV1.2 and Syphilis Combo Rapid Test for Syphilis	Method	TPPA		Total Results
		Positive	Negative	
HIV1.2 and Syphilis Combo Rapid Test for Syphilis	Results			
	Positive	253	1	254
	Negative	2	344	346
Total Result		255	345	600

Relative Sensitivity: 99.2% (95%CI*: 97.2%-99.9%)

*Confidence Intervals

Relative Specificity: 99.7% (95%CI*: 98.4%-100%);

Accuracy: 99.5% (95%CI*: 98.5%-99.9%)

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of different specimens containing different concentrations of HIV 1.2 antibody and syphilis antibody. The negative, positive values were correctly identified 100% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same three different specimens containing different concentrations of HIV 1.2 antibody and syphilis antibody. Three specimens: a negative, a low titer positive and a high titer positive. Three different lots of the HIV 1.2 and Syphilis Combo Rapid Test (Whole Blood/Serum/Plasma) have been tested over a 3-days period using above negative and positive specimens. The specimens were correctly identified 100% of the time.

Cross-reactivity

The HIV 1.2 and Syphilis Combo Rapid Test has been tested by anti-HAMA IgG, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-HCV 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, anti-HSV 1 IgG, anti-HSV 1 IgM, anti-HSV 2 IgG and anti-HSV 2 IgM positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to HIV 1.2 antibody and syphilis antibody negative and positive specimens.

Acetaminophen:	20 mg/dL	Caffeine:	20 mg/dL
Acetylsalicylic Acid:	20 mg/dL	Genitisc Acid:	20 mg/dL
Ascorbic Acid:	2 g/dL	Albumin:	2 g/dL
Creatin:	200 mg/dL	Hemoglobin:	1000 mg/dL
Bilirubin:	1 g/dL	Oxalic Acid:	60 mg/dL

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

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Index of Symbols

	Consult Instructions For Use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Do not use if package is damaged		Manufacturer		

Number: 145723302

Effective Date: 2020-07-15

