Syphilis/HIV 1.2.O Combo Rapid Test Cassette (Serum /Plasma)
Package Insert

REF IISC-325	English

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

【INTENDED USE】

The Syphilis/HIV 1.2.O Combo Rapid Test Cassette (Serum /Plasma) is a rapid chromatographic immunoassay for the qualitative detection of *antibodies to HIV type 1, type 2, subtype O and syphilis- antibodies (IgG and IgM) to Treponema Pallidum(TP) in serum or plasma.*

【SUMMARY】

The HIV 1.2.O Rapid Test (Serum/Plasma) 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 1.2.O Rapid Test Cassette (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibodies to HIV type 1, type 2, and/or Subtype O in serum or plasma specimen.

The Syphilis Rapid Test (Serum/Plasma) utilizes a double antigen combination of a Syphilis antigen coated particle and Syphilis antigen immobilized on membrane to detect TP antibodies (IgG and IgM) qualitatively and selectively in serum or plasma.

Treponema Pallidum (*TP*) is the causative agent of the venereal disease Syphilis. TP is a spirochete bacterium 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 numbers 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. One study reported a substantial epidemiological correlation between the acquisition and transmission of the HIV virus and Syphilis.

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.[9]

【PRINCIPLE】

The HIV 1.2.O Rapid Test (Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibodies to HIV-1, HIV-2, and Subtype O in 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 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 colored line will appear in the test line region; if the specimen contains antibodies to HIV-1 and/or Subtype O, and HIV-2, two colored 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 colored line will 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.

The Syphilis Rapid Test (Serum /Plasma) is a qualitative membrane based immunoassay for the detection of TP antibodies (IgG and IgM) in serum or plasma. In this test procedure, recombinant Syphilis antigen is immobilized in the test line region of the test. After specimen is added to the specimen well of the test Cassette, it reacts with Syphilis antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized Syphilis antigen. The double antigen test format can detect both IgG and IgM in specimens. If the specimen contains TP antibodies, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain TP antibodies, a colored line will not appear in this 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 cassette contains HIV 1.2.O recombinant antigens conjugated particles, HIV1.2.O recombinant antigens coated on one membrane and Syphilis antigen coated particles and Syphilis antigen coated on the other 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 kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure 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.
- 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 Syphilis/HIV 1.2.O Combo Rapid Test Cassette (Serum/Plasma) can be performed using either serum or plasma.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- 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 federal regulations for transportation of etiologic agents.

【MATERIALS】

Materials provided

- Test cassettes
- Buffer
- Droppers
- Package insert

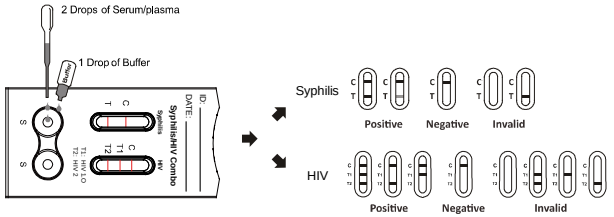
Materials required but not provided

- Specimen collection containers
- Centrifuge (for plasma only)
- Timer

【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 test cassette on a clean and level surface. Hold the dropper vertically and transfer **2 drops of serum or plasma (approximately 50µL)** to the specimen area, then add **1drop of buffer (approximately 40µL)**, respectively. Start the timer. See the illustration below.
3. Wait for the colored line(s) to appear. The test result should be read at **10 minutes**. Do not interpret the result after **20 minutes**.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

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

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

NEGATIVE: One color line appears in the control region (C). No apparent red or pink line appears in the test 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 cassette. 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 color line appearing in the control region (C) is an internal positive 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. This test is for in vitro diagnostic use only.
2. This test has been developed for testing serum/plasma specimens only. The performance of the test using other specimens has not been substantiated.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of HIV 1.2.O antibody or syphilis antibody.
4. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
5. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of HIV1.2.O and/or syphilis infection.

【EXPECTED VALUES】

The Syphilis/HIV 1.2.O Combo Rapid Test Cassette (Serum /Plasma) has been compared with leading commercial EIA tests for Syphilis and HIV , respectively. The correlation between these two systems is 99.8%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

1. HIV 1.2.O

The HIV 1.2.O Rapid Test (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.O Rapid Test (Serum/Plasma) is >99.9% and the relative specificity is 99.8%.

Method		ELISA		Total Results
HIV 1.2.O Rapid Test(Serum /Plasma)	Results	Positive	Negative	
	Positive	100	1	101
	Negative	0	399	399
Total Result		100	400	500

Relative Sensitivity: >99.9% (95%CI*: 97.0%-100%) *Confidence Intervals
Relative Specificity: 99.8% (95%CI*: 98.6%-100%);
Accuracy: 99.8% (95%CI*: 99.0%-100%).

2. Syphilis

The Syphilis Rapid Test (Serum /Plasma) has correctly identified specimens of a performance panel and has been compared to a leading commercial TPPA Syphilis test using clinical specimens. The results show that the relative sensitivity of the Syphilis Rapid Test C (Serum /Plasma) is >99.9% and the relative specificity is 99.7%.

Method		ELISA		Total Results
Syphilis Rapid Test (Serum /Plasma)	Results	Positive	Negative	
	Positive	205	1	164
	Negative	0	336	336
Total Result		205	337	500

Relative Sensitivity: >99.9% (95%CI*: 98.2%-100%) *Confidence Intervals
Relative Specificity: 99.7% (95%CI*: 98.4%-100%)
Accuracy: 99.8% (95%CI*: 99.0%-100%)

Precision

Intra-Assay

Within-run precision has been determined by using 20 replicates of four different specimens containing different concentrations of HIV 1.2.O antibody and syphilis antibody. The negative, positive values were correctly identified 100% of the time.

Inter-Assay

Between-run precision has been determined by 20 independent assays on the same four different specimens containing different concentrations of HIV 1.2.O antibody and syphilis antibody. Three specimens: a negative, a low titer positive and a high titer positive. Three different lots of the Syphilis/HIV 1.2.O Combo Rapid Test (Serum/Plasma) have been tested over a 3-month period using above negative and positive specimens. The specimens were correctly identified 100% of the time.

Cross-reactivity

The HIV 1.2.O Rapid Test (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.

The Syphilis Rapid Test (Serum/Plasma) has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HCV,HIV, 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 1.2.O antibody and syphilis antibody 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:	1000mg/dL
Bilirubin:	1g/dL	Oxalic Acid:	60mg/dL

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

【BIBLIOGRAPHY】

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Index of Symbols

⚠	Attention, see instructions for use	Σ	Tests per kit	②	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		

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Number: 145367300
Effective date: 2016-08-25