Cellex

REF **Catalog Number：5118C**

IVD **In Vitro Diagnostic**

INTENDED USE

The Cellex qHIV/Syphilis Ab Cassette Combo Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies to HIV-1, HIV- 2 and Treponema pallidum (Tp) in human serum, plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HIV and Tp. Any reactive specimen with the Cellex qHIV/Syphilis Ab Cassette Combo Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

Human immunodeficiency virus type I and type II (HIV-1 and HIV-2) are enveloped, single-stranded, positive-sense RNA viruses. The two types of HIV have significant variation in sequence. HIV-1 has been divided into three groups: group M (for major), including at least ten subtypes (A through J); group O (for outlier); and group N (for non-M, non -O). Similarly, HIV-2 has been classified into at least five subtypes (A through E). Worldwide, most HIV infections are HIV-1, whereas HIV-2 has largely been confined to persons in or from West Africa. HIV-1 and HIV-2 have the same routes of transmission with both causing acquired immunodeficiency syndrome (AIDS).

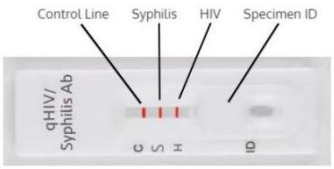
Tp is a spirochete bacterium causing the sexually transmitted disease syphilis, rates of which have been increasing according to the CDC. In 1995, WHO reported 12 million new cases of syphilis[6]. Recent evidence suggests that STDs increase HIV shedding in the genital tract of HIV positive individuals making early syphilis detection of great importance.

Serological tests detecting antibodies (IgG, IgM and IgA) to HIV viruses and Tp are commonly used by clinical laboratories as evidence of infection to aid in the diagnosis of AIDS and or Syphilis.

The Cellex qHIV/Syphilis Ab Cassette Combo Rapid Test can simultaneously detect IgG, IgM and IgA antibodies to HIV-1, HIV-2 and Tp in patient serum, plasma or whole blood within 15 minutes. The test can be performed by personnel with minimal training without cumbersome laboratory equipment.

TEST PRINCIPLE

The Cellex qHIV/Syphilis Ab Cassette Combo Rapid Test is a lateral flow immunochromatographic Rapid Test. The test cassette consists of: 1) a burgundy colored conjugate pad containing HIV 1+2 antigens conjugated with colloidal gold (HIV 1+2 conjugates), recombinant Tp antigens conjugated with colloidal gold (Tp conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test lines (HIV line and SY line) and a control line (C line). The HIV line is pre- coated with HIV 1+2 antigen, the SY line is pre-coated with recombinant Tp antigens and the C line is pre-coated with goat anti-rabbit IgG antibody.



When an adequate volume of test specimen is dispensed into the sample well of the cassette, it migrates by capillary action across the cassette. HIV-1 or HIV-2 antibodies, if present in the specimen, migrate through the conjugate pad where they bind to the HIV 1+2 conjugates. The immunocomplex is then captured on the membrane by the pre-coated HIV 1+2 antigens forming a burgundy colored HIV line, indicating a HIV 1+2 positive or reactive test result. Absence of this HIV line in the test region suggests an HIV-1 and HIV-2 antibody negative or nonreactive test result.

Similarly, if anti-Tp antibodies are present in the specimen, they will bind to the Tp conjugates. The immunocomplex is then captured on the membrane by the pre -coated Tp antigen forming a burgundy colored SY line, indicating a Tp antibody positive test result. Absence of the SY line suggests a negative result or nonreactive result for the Tp antibody test.

The test contains an internal control (C line) which should exhibit a burgundy colored immunocomplex line of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless of color development on the test lines. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
a. One cassette device
b. One desiccant
2. Plastic droppers (25pcs)
3. Sample diluent (25 vial, 320ul/vial)
4. One package insert (instruction for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

1. HIV Ab Positive Control
2. HIV Ab Negative Control
3. Syphilis Ab Positive Control
4. Syphilis Ab Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Lancing device for whole blood test

WARNINGS AND PRECAUTIONS

For *in Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow instructions may provide inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the Rapid Test.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15℃-30℃) before use.
5. Do not use components from any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle negative and positive controls in the same manner as patient specimens.
12. The test results should be read within 15 minutes after a specimen is applied to the sample well. Reading the test after 15 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2℃ - 30℃. The positive and negative controls should be kept at 2℃ - 8℃. If stored at 2℃ - 8℃, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30℃.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma

Step1: Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer ®) by venipuncture.
Step 2: Separate the plasma by centrifugation.
Step 3: Carefully withdraw the plasma into a new pre-labeled tube.

Serum

Step 1: Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
Step 2: Allow the blood to clot.
Step 3: Separate the serum by centrifugation.
Step 4: Carefully withdraw the serum into a new pre-labeled tube.
Test specimens as soon as possible after collecting. Store specimens at 2℃ - 8℃ if not tested immediately for up to 5 days. The specimens should be frozen at -20℃ for longer storage.
Avoid multiple freeze- thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

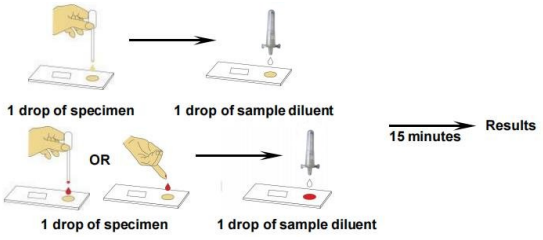
Whole Blood

Drops of whole blood can be obtained by either finger tip puncture or venipuncture. Do not use hemolyzed blood for testing.

Whole blood specimens should be stored in refrigeration (2℃ - 8℃) if not tested immediately. The specimens must be tested within 24 hours of collection.

RAPID TEST PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing Rapid Test.
Step 2: When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface.
Step 3: Label the device with the specimen's ID number.
Step 4: Fill the plastic dropper with the specimen.
Holding the dropper vertically, dispense 1 drop (about 30~45 μL) of serum/plasma or 1 drop of whole blood (about 30~45 μL) into the sample well making sure there are no air bubbles.
Immediately add 1 drop (about 30~45 μL) of Sample Diluent into the sample well.



Step 5: Set up timer.
Step 6: Results can be read within 15 minutes. Positive results may be visible within 1 minute.
Do not read the result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

1. Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding the specimen and the sample diluent. If the C line does not develop, review the whole procedure and repeat the test with a new device.
2. External Control: Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the Rapid Test, particularly under the following circumstances:

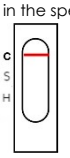
New operator uses the kit, prior to performing the testing of the specimens.

a. A new lot of test kits is used.
b. A new shipment of kits is used.
c. The temperature used during storage of the kits fall outside of 2℃- 30℃.
d. The temperature of the test area falls outside of 15℃-30℃.
e. To verify a higher than expected frequency of positive or negative results.
f. To investigate the cause of repeated invalid results.

INTERPRETATION OF RAPID TEST RESULT

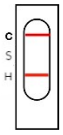
1. NEGATIVE RESULT:

If only the C line is developed, the test indicates that neither anti-HIV nor anti-Tp antibodies are present in the specimen. The result is negative.

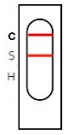


2. POSITIVE OR REACTIVE RESULT:

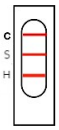
2.1 If both the C and the H lines are developed, the test indicates the presence of anti-HIV antibodies in the specimen. The result is positive for HIV antibodies.



2.2 If both the C and the S lines are developed, the test indicates the presence of anti-Tp antibodies in the specimen. The result is anti-Tp antibody positive.



2.3 In addition to the presence of the C line, if both the H line and the S line are developed, the result is both HIV antibody and Tp antibody positive or reactive.



Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. INVALID:

If no C line is developed, the Rapid Test is invalid regardless of color development on the test lines as indicated below. Repeat the Rapid Test with a new device.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance for HIV 1+2 Ab Test

A total of 350 clinical specimens were tested by the HIV/Syphilis Ab Combo Rapid Test and by a commercial HIV 1+2 Rapid Test as reference. Comparison for all subjects is shown in the following table:

	HIV/Syphilis Ab Combo Rapid Test		
Reference	**Positive**	**Negative**	**Total**
Positive	104	1	105
Negative	2	243	245
Total	106	244	350

Relative Sensitivity: 99%, Relative Specificity: 99.2%, Overall Agreement: 99.1%

2. Clinical Performance for Syphilis Antibody Test

A total of 350 clinical specimens were tested by the HIV/Syphilis Ab Combo Rapid Test and by a commercial Syphilis Ab Rapid Test as reference. Comparison for all subjects is shown in the following table.

	HIV/Syphilis Ab Combo Rapid Test		
Reference	**Positive**	**Negative**	**Total**
Positive	103	2	105
Negative	0	245	245
Total	103	247	350

Relative Sensitivity: 98.1%, Relative Specificity: 100%, Overall Agreement: 99.4%

LIMITATIONS OF TEST

1. The Rapid Test Procedure and the Interpretation of Rapid Test Result sections must be followed closely when testing for the presence of anti-HIV 1+2 and anti-Tp antibodies in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Cellex qHIV/Syphilis Ab Cassette Combo Rapid Test is limited to the qualitative detection of anti-HIV and anti-Tp antibodies in human serum, plasma or whole blood. The intensity of the test line does not correlate with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable anti-HIV and/or anti-Tp antibody. However, a negative test result does not preclude the possibility of exposure to or infection with HIV and/or Tp.
4. A negative result can occur if the quantity of the anti-HIV and/or anti-Tp antibody present in the specimen is below the detection limits of the Rapid Test or the antibodies are not present during the stage of disease in which a sample is collected.
5. If the symptoms persist while the result from Cellex qHIV/Syphilis Ab Cassette Combo Rapid Test is negative or non-reactive, it is recommended to re-sample the patient a few weeks later or test with an alternative test device.
6. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

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Index of Symbols

	Consult instructions for use	IVD	For in vitro diagnostic use only		Use by
REF	Catalog #	LOT	Lot Number	Σ	Tests per kit
2℃ 30℃	Store between 2-30℃	EC REP	Authorized Representative		Do not reuse
	Manufacturer		Date of manufacture		

Cellex, Inc.
76 TW Alexander Drive,
Research Triangle Park, NC 27709-0002, USA
Tel: 1-919-314-5535,
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