Core tests® HIV 1+2 Test Cassette (WB)

For Professional Use
Specimen: Whole Blood/Serum/Plasma
Format: Cassette

INTENDED USE

HIV 1+2 Test is a rapid chromatographic immunoassay for the qualitative detection of antibody to Human Immunodeficiency Virus (HIV) type-1 and/or type-2 in whole blood or serum/pla ma. It is intended for use in medical institution as an aid for the diagnosis and management of patients related to infection with HIV and for screening of blood donors, or blood products as well.

SUMMARY

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virus is surrounded by a lipid envelope that is derived from host cell membrane. Several viral glycoprotiens are on the envelope. Each virus contains two copies of positive-sense genomic RNAs. Patients with HIV-1 has been isolated from patients with AIDS and AIDS-related complex and from healthy individuals with a high potential risk for developing AIDS. Patients with HIV-2 has been isolated from West Africa AIDS patients and from seropositive asymptomatic individual. Both HIV-1 and HIV–2 elicit an immune response. Detection of HIV antibodies in whole blood or 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. Despite the difference in their biological characteristics, serological activities and genome sequences of HIV-1 and –2 show strong antigenic cross-reactivity. Most HIV-2 positive sera can be identified by using HIV-1 based serological tests.
HIV 1+2 Test is a rapid test to qualitatively detect antibodies to HIV-1 and/or HIV- 2 in whole blood or serum/plasma specimen. The test utilizes a combination of recombinant HIV proteins- coated gold conjugate and recombinant HIV proteins to selectively detect antibody to the HIV-1 and HIV-2 in whole blood, serum or plasma. The genes for envelope proteins (gp36/41) encode the recombinant HIV proteins that are used in the test kits.

PRINCIPLE

HIV 1+2 test contains a membrane strip, which is pre-coated with recombinant HIV 1 capture antigen (gp41) on test line 1 region and with recombinant HIV 2 capture antigen (gp36) on test band 2 region respectively. The recombinant HIV 1/2 antigen (gp41 and gp36) - colloidal gold conjugate and blood sample moves along the membrane chromatographically to the test region (T) and forms a visible line as the antigen-antibody-antigen gold particle complex forms with high degree of sensitivity and specificity.
This test device has letters of 1, 2 and C as "Test Line1 (HIV-1)", "Test Line2 (HIV-2)" and "Control Line" on the surface of the cassette. Both the Test Lines and Control Line in result window are not visible before applying any sample. The Control Line is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working.
Absence of the colored line in the control region indicates an invalid result regardless of the presence or absence of the test line.

MATERIALS PROVIDED

HIV 1+2 test contains following items to perform the assay:
1. HIV 1+2 test device
2. Instruction for use
3. Chasing buffer
4. Sterile lancet
5. Pipette

A complete set for home use may also contain the following accessories in a separate poly bag:
1. Pipette
2. Alcohol pad
3. Bandage

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Sample container
3. Glove

WARNING AND PRECAUTIONS

1. Read instruction for use carefully before performing this test.
2. For in vitro diagnostic use only.
3. Do not use the test device beyond the expiration date.
4. The test device should remain in the sealed pouch until use. Do not use the test device if the pouch is damaged or the seal is broken.
5. Do not reuse the device.
6. Treat and properly handle the specimen and used device as if they were potentially infectious. Dispose all specimen and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
7. There should be no eating, drinking or smoking where specimen are being handled.
8. Do not mix and interchange different specimen.
9. Wear disposable gloves, lab coat and eye protection while handling potentially infectious material and performing the assay. Wash hands thoroughly afterwards.
10. Clean spills thoroughly using an appropriate disinfectant.
11. Keep out of children's reach.
12. Do not swallow the desiccant.

SPECIMEN PREPARATION

Whole Blood Specimen

1. Clean the area to be lanced with alcohol prep pad.
2. Squeeze the fingertip and pierce it with the sterile lancet.
3. Wipe away the first drop of blood with sterile gauze or cotton.
4. Using a disposable pipette, collect blood from the puncture site.

The whole blood may be used for testing immediately or may be stored at 2-8℃ for two days. Specimen that have been refrigerated must be equilibrated to room temperature before testing.

Serum or Plasma Specimen

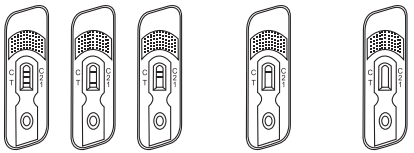
1. Centrifuge whole blood to get serum or plasma specimen.
2. If specimen is not tested immediately,it should be refrigerated at 2-8℃. For storage period greater than three days, freezing is recommended. Such specimen should be brought and equilibrated to room temperature prior to use.
3. Serum containing precipitate may yield inconsistent test result. Such specimen must be clarified prior to assaying.

TEST PROCEDURE

Review specimen preparation instructions and bring the pouched test device together with patient's specimen or controls to room temperature (15-30℃) prior to testing. Do not open the pouch until ready to perform the assay.

1. Remove the test device from its protective pouch. Label the devices with patient or control identifications. Lay it on a flat, clean and dry surface.
2. Use the pipette to draw and slowly add 1 drop of whole blood/serum/plasma to the sample well.
3. Hold the buffer bottle vertically and add 1 drop buffer to the sample well. Or use pipette, change a new one to avoid cross-contamination. Draw and transfer 2-3 drops of buffer to the sample well.
4. Read results between 10-15 minutes. Do not read results after 20 minutes.

INTERPRETATION OF RESULTS



POSITIVE: The presence of not less than two color lines ("1" , "2" and "C") within the result window, no matter which line appears first, indicates a positive result for HIV-1 or / and HIV-2 respectively.
Regarding the positive results for both HIV-1 and HIV-2 in one patient, it is possible for reasons as follows:

1. There is the homology in the amino acid sequence of HIV type-1 and type-2. So, it is possible that the test results appear the positive results for HIV-1 and HIV-2 in one patient, simultaneously.
2. Provisionally, you can conclude virus type according to the line density. If the line density of type-1 is darker than that of type-2 in the result window, you can read as HIV-1 positive. If the line density of type-2 is darker than that of type-1 in the result window, you can read as HIV-2 positive. If you want to determine virus type or co-infection exactly, you should perform the confirmatory assay (e.g Western blot etc.).

NEGATIVE: The presence of only one line on the control region indicates a negative result.

INVALID: Control Line fails to appear.

NOTE: 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 device. If the problem persists, please contact your local distributor.

QUALITY CONTROL

Although the testing device contains an internal quality control (colored line in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

The test device should be stored at 2-30℃ in the sealed pouch. Avoid humidity, heat and direct sunlight. The test device is stable through the expiration date printed on the sealed pouch. DO NOT FREEZE.

LIMITATION OF THE TEST

1. This product is an in vitro diagnostic test designed for professional use only.
2. Humidity and temperature can adversely affect results.
3. There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
4. Although the test demonstrates superior accuracy in detecting HIV infections, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1. Diagnostic Sensitivity

A multi-center prospective study was conducted to evaluate the diagnostic sensitivity of HIV 1+2 Test in whole blood/serum/plasma specimens. A total of 520 positive samples from patients clinically diagnosed as HIV infected were tested with the HIV 1+2 Test and the comparedwith that of a CE marked HIV 1/2 test. Of the 520 HIV positive samples, 518 were tested positive and 2 were tested negative by the HIV 1+2 Test. The two samples that were tested negative were further confirmed positive by CLIA. The diagnostic sensitivity of HIV 1+2 Test was 99.61% (51 8/520).

Table 1 Summary of Diagnostic Sensitivity of HIV 1+2 Test

Genotype/Subtype		Results of HIV 1+2 Test		Results of CE Marked Test		Subtotal
		Positive	Negative	Positive	Negative	
HIV-1	A	5	0	5	0	5
	B	12	0	12	0	12
	C	5	0	5	0	5
	D	4	0	4	0	4
	F	5	0	5	0	5
	G	4	0	4	0	4
	B	12	0	12	0	12
	E	4	0	4	0	4
	AE	10	0	10	0	10
	AG	5	0	5	0	5
	BC	14	0	14	0	14
	Unknown subtype	321	1	322	0	322
HIV-2		117	1	118	0	118
Subtotal		518	2	520	0	520

2. Diagnostic Specificity

A multi-center prospective study was conducted to evaluate the diagnostic specificity of the HIV 1+2 Test. A total of 1710 negative samples were collected from different populations including blood donors, inpatients, pregnant women, and patients with potentially interfering diseases. These samples were tested with the HIV 1+2 Test and the results were compared with that of a CE marked HIV 1/2. Of the 1710 negative samples, 5 were tested positive by HIV 1+2 Test. The diagnostic specificity of HIV 1+2 Test was 99.71 % (1705/1710), and the false positive rate was 0.29% (5/1710).

Table 2 Summary of Diagnostic Specificity of HIV 1+2 Test.

	Results of HIV 1+2 Test		Results of CE Marked Test		Subtotal
	Negative	Positive	Negative	Positive	
Blood Donors	1097	3	1098	2	1100
inpatients	204	1	205	0	205
Pregnant Women	205	0	204	1	205
potentially interfering diseases	199	1	199	1	200
Subtotal	1705	5	1706	4	1710

3. Analytic Sensitivity

Reactivity with Anti-HIV 1/2 Performance Panel and Worldwide Panel

A Anti-HIV 1/2 performance panel consisting of 15 members and a Worldwide panel consisting of 20 members derived from multiple geographics representing ten HIV-1 Group M subtypes (A，B，C, CRF01_ AE，CRFO2_ AG, D,F, G, H, and J) and two HIV-2, were tested with the HIV 1+2 Test and CE marked HIV 1/2 tests. Study results demonstrated that HIV 1+2 Test was capable of detecting HIV 1+2 and its sensitivity was similar to that of the CE licensed HIV 1/2 tests.

4. Analytic Specificity

In order to evaluate the specificity of the HIV 1+2 Test, 115 normal negative specimens and 85 negative specimens containing the following seromarkers were tested: hepatitis C virus (HCV)，hepatitis B virus (HBsAg, anti-HBc IgG/IgM, and HBsAb), hepatitis A virus IgM (anti-HAV), herpes simplex virus IgG (HSV), cytomegalovirus (CMV) IgG/IgM, Epstein-Barr Virus (EBV) IgG/IgM, human T-Lymphotrophic virus (HTLV)，rubella IgM (RV)，anti-E. Coli, Helicobacter pylori (HP) IgG/IgM, syphilis reagin (RPR/TPPA), mycoplasma IIgM，C-reactive protein (CRP)，antistreptolysin O titre (ASOT), rheumatoid factor (RF). Two tests from each of the two lots of HIV 1 +2 Test were carried out for each of the panel samples. Results demonstrated that HIV 1 +2 Test has no significant cross-reactivity with the seromarkers listed above.

5. Interference

The following substances and conditions were found not to interfere with the test. List of potentially interfering compounds (chemical analytes and biological analytes) and concentrations tested are as follows:

Chemical analytes	Concentrations	Chemical analytes	Concentrations
Acetaminophen	200 ug/ml	Methaqalone	200 ug/ml
Acetylsaclicylic Acid	200 ug/ml	Pendimetrazine	200 ug/ml
Amikacin	200 ug/ml	Penicillin G	200 ug/ml
Ascorbic acid	200 ug/ml	Quinine	200 ug/ml
Aspartame	200 ug/ml	Ranitidine	200 ug/ml
Atropine Sulfate	200 ug/ml	Sodium Salicylate	200 ug/ml
Benzoic Acid	200 ug/ml	Tryptophan	200 ug/ml
Caffeine	200 ug/ml	Tetracycline	200 ug/ml
Deoxyephedrine	200 ug/ml	Tetrahydrozoline	200 ug/ml
Dextromethorphan	200 ug/ml	Ethanol	1%
EDTA	800 ug/ml	Methanol	1%
Gentesic acid	200 ug/ml	Heparin	1%
Histamine	200 ug/ml	Citrate	3.2%
Biological analytes	Concentrations	Biological analytes	Concentrations
Albumin	2 mg/ml	Bilirubin	2 mg/ml
Glucose	2 mg/ml	Hemoglobin	2 mg/ml

6. Reproducibility

Three lots of the HIV 1+2 Test were tested with both positive and negative samples to evaluate its precision. The resultant data indica ed that all three lots of the test were able to produce accurate and consistent results.

REFERENCES

1. Centers for Disease Control: Provisional Public Health Service inter-agency recommendations for screening donated blood and plasma for antibody to the virus causing acquired immunodeficiency syndrome. Morbidity and Mortality Weekly Rep 34:5-7, 1985.
2. Coffin J, Haase A, Levy JA, et al: What to call the AIDS virus? Nature 321:10, 1986.
3. Clavel F, Guetard D, Brun-Vezinet F: Isolation of a new human retrovirus from West African patients with AIDS. Science 233:343-346, 1986.
4. Schim van der Loeff MF and Aaby P: Towards a better understanding of the epidemiology of HIV-2. AIDS 13 (Suppl. A):S69-S84, 1999.
5. Quinn TC, Zacarias FRK, St. John RK: AIDS in the Americas: an emerging public health crisis. New Engl J Med 320:1005-1007, 1989.
6. Guyader M, Emerman M, Sonigo P, et al: Genome organization and transactivation of the human immunodeficiency virus type 2. Nature 326:662-669, 1987.
7. Cabrian K, Shriver K, Goldstein L, et al: Human immunodeficiency virus type 2: a review. J Clinical Immunoassay 11:107-114, 1988.
8. Charneau P, Borman AM, Quillant C, et al: Isolation and envelope sequence of a highly divergent HIV-1 isolate: definition of a new HIV-1 group. Virology 205:247-253, 1994.
9. Simon F, Mauclère P, Rogues P, et al: Identification of a new human immunodeficiency virus type 1 distinct from group M and group O. Nature Medicine 4:1032-1037, 1998.

INDEX OF SYMBOLS

	Consult instructions for use		Do not re-use
IVD	In vitro diagnostic medical device		Use-by date
	Store at 2-30℃	LOT	Batch code
n	Contains sufficient for <n>tests	REF	Catalogue number

MANUFACTURER CONTACT INFORMATION

Core Technology Co.,Ltd.
Room 100, C Building, No.29 Life Park Rd.,
Changping District, Beijing 102206, P.R. China
Tel:+86-10-69390616
Email:info@coretests.com
Fax:+86-10-69390660

Digitally signed by Guțan Ghenadie
Date: 2022.10.31 09:15:17 EET
Reason: MoldSign Signature
Location: Moldova