Instructions For Use

* Please carefully read the instructions before use

One Step HIV 1+2 Test

(HIV 1+2 Test Cassette)

Format: Cassette

Specimen: Serum/Plasma

INTENDED USE

The One Step 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 serum or plasma. 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 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. 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.

The One Step HIV 1+2 Test is a rapid test to qualitatively detect antibodies to HIV-1 and/or HIV–2 in serum or 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 serum or plasma. The genes for envelope proteins (gp36/41) encode the recombinant HIV proteins that are used in the test kits.

PRINCIPLE

The test is an antibody-capture immunochromatographic assay, detecting HIV antibodies in blood samples. The membrane is pre-coated with recombinant HIV antigens on the test line region (T) and goat anti-mouse on the control line region (C). During testing, the specimen is allowed to react with the gold colored conjugate (recombinant HIV antigens-colloidal gold conjugate), which has been pre-dried on the test. The mixture then moves upward on the membrane chromatographically by capillary action. For a positive result, a pink-colored line with the recombinant HIV antigens-colored conjugate complex will form in the test line region (T) of the membrane. Absence of this pink-colored line in the test line region (T) indicates a negative result.

To serve as an internal process control, the control line should always appear in the control region (C) after the test is completed indicating that the test is performed properly and the reagents of the test 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

One Step HIV 1+2 Test contains the following items to perform the assay:

1. One Step HIV 1+2 Test Device
2. Instruction for use
3. Buffer
4. Pipette 5. Sterile lancet 6. Alcohol wipes

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 specimens and used device as if they were potentially infectious. Dispose all specimens 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 specimens are being handled.
8. Do not mix and interchange different specimens.
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

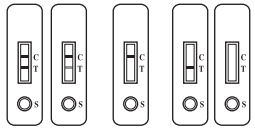
1. Centrifuge whole blood to get serum or plasma specimen.
2. If specimen is not tested immediately,it should be refrigerated at 2-8℃. For storage period greater than three days, freezing is recommended. Such specimen should be brought and equilibrated to room temperature prior to use.
3. Serum containing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

TEST PROCEDURE

Review specimen preparation instructions and bring the pouched test device together with patients specimens 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 device 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 serum/plasma to the sample well.
3. Hold the buffer bottle vertically and add 1 drop of 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. Wait for colored lines to appear within 10-15 minutes. Do not interpret result after 20 minutes.

INTERPRETATION OF RESULTS



Positive Negative Invalid

POSITIVE: Two distinct colored lines appear, one in the control region (C) and another one in the test region (T).The color intensity of the test line may be weaker or stronger than that of the control line.

NEGATIVE: Only one colored line appears in the control region (C). No line is visible in the test region (T).

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 band 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 One Step HIV 1+2 Test in serum/plasma specimens. A total of 520 positive samples from patients clinically diagnosed as HIV infected were tested with the One Step HIV 1+2 Test and the test results were compare with 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 One Step HIV 1+2 Test. The two samples that were tested negative were further confirmed positive by CLIA. The diagnostic sensitivity of One Step HIV 1+2 Test was 99.62% (518/520).

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

Genotype/Subtype		Results of One Step 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 One Step 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 One Step 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 One Step HIV 1+2 Test. The diagnostic specificity of One Step 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 One Step HIV 1+2 Test.

	Results of Coretests™ One Step 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, CRF02_AG, D, F, G, H, and J) and two HIV-2, were tested with the Coretests™ One Step HIV 1+2 Test and CE marked HIV 1/2 test. Study results demonstrated that Coretests™ One Step 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 test.

4. Analytic Specificity

In order to evaluate the specificity of the Coretests™ One Step 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 IgM, C-reactive protein (CRP), antistreptolysin O titre (ASOT), rheumatoid factor (RF). Two tests from each of the two lots of Coretests™One Step HIV 1+2 Test were carried out for each of the panel samples. Results demonstrated that Coretests™ One Step 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
Acetylsadicylic 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 Coretests™One Step HIV 1+2 Test were tested with both positive and negative samples to evaluate its precision. The resultant data indicated 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

	Do not re-use		Manufacturer
IVD	In vitro diagnostic medical device		Use-by date
2℃ 30℃	Store at 2-30℃		Consult instructions for use
EC REP	Authorized representative in the European Community	LOT	Batch code
Σ n	Contains sufficient for <n>tests	CE	CE Mark
	Caution	REF	Catalogue number

MANUFACTURER CONTACT INFORMATION

Core Technology Co., Ltd.
Registered Address:
Room 100, C Building, No.29 Life Park Rd.,
Changping District, Beijing 102206, China
Manufacture Address:
No.30, Area 9,Douda Avenue,Fangshan District,Beijing,102433,P.R. China
Tel: +86(10)69390616
Fax:+86(10)69390660
E-mail: sales@coretests.com

EC REP Wellkang Ltd
Enterprise Hub,NW Business Complex,
7 Lagmore Rd. Derry, BT48 8SE, Northern Ireland UK

Doc No.RR33C1309
Ver.4.0
Eff.Date: Oct. 2020