NEWSCEN
NEWSCEN COAST BIO-PHARMACEUTICAL CO., LTD.
NO. 65 Sixth Ave, TEDA Tianjin, 300457, P. R. China
Web(EN): www.newscenbiotech.com
E-mail: export@newscen.com

CE 0123 IVD REF HIV$_3$-29200103000 Version: B/1 Revision Date: 14/12/2020

Newscen HIV (1+2) Antibody Rapid Test

【For the qualitative detection of HIV (1+2) antibodies in serum / plasma and whole blood】

(Single use test cassette)

The instruction must be read carefully and completely prior to the use of Newscen HIV (1+2) Antibody Rapid Test. Instruction must be followed carefully. If directions are not followed exactly, inaccurate test result may occur. Before performing testing, all operators must read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, Hepatitis C Virus and Other Blood-Borne Pathogens in Health-Care Settings.

INTENDED USE

Newscen HIV (1+2) Antibody Rapid Test is a single use, rapid immunoassay for qualitative detection of antibodies to Human Immunodeficiency Virus type 1 and 2 (HIV-1/ 2) in human serum, plasma or whole blood collected from vein or fingertip. It is intended for use in medical institutions by trained staff.

PRINCIPLE

HIV-1 (gp41 and gp120) and HIV-2 (gp36) specific recombinant antigens are separately precoated onto the membrane in zone 1 and 2 as the capture reagent on the test zone. During the test, specimen is allowed to react with the colloidal gold particles, which have been conjugated with HIV-1 and HIV-2 specific recombinant antigens. Antibodies to HIV-1 and/ or HIV-2, if present, will specifically bind to colloidal gold-antigen complex. When the colloidal gold-antigen-antibody complexes move to the test zone, they will specifically bind to the precoated antigens. At the same time, a red colored line will develop in zone 1 and/ or 2 on the membrane. Absence of these red colored lines in the test zone (1 and 2) suggests a negative result. To serve as a procedural control, red colored line in the control zone will always appear regardless of the presence of antibodies to HIV-1/ HIV-2.

REAGENTS AND MATERIALS PROVIDED

Each kit contains:

1. 1 test cassette (individually pouched)
2. Each pouch contains one cassette with one desiccant bag
3. One bottle of diluent buffer (1mL)
4. 1 disposable plastic dropper

Note: The droppers are produced by Shandong Aosaite Medical Devices Co., Ltd., and the manufacturer's address is No. 3 Beihuan Road, Chengwu County, Shandong, China.

5. Instruction for use
6. Sterile lancet
7. Alcohol pad

Table 1 Manufacturer information of purchased components

	Sterile lancet	Alcohol pad
CE 0123	CERTIFICATE No. G2 072777 0009 Rev.01	CE 0123 CERTIFICATE No. G2S 103710 0002 Rev.00
	Ningbo Medsun Medical Co., Ltd. No.55 Jinxi Road, Zhenhai 315221 Ningbo People's Republic of China	Jiangsu Sunclean Medical Co., Ltd. No. 11 Fenghuang South Road, Hutang Town, Wujin District, 213162 Changzhou City, Jiangsu Province, People's Republic of China
EC REP	Shanghai International Holding Corp. GmbH(Europe) Eiffestraβe 80 20537 Hamburg, GERMANY	EC REP MedPath GmbH Mies-van-der-Rohe-Strasse 8 80807 Munich, Germany

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or stopwatch
2. Blood collection devices, for the testing of venous whole blood, serum or plasma
3. Biohazard disposal container
4. Disposable gloves

For fingerstick samples, the following materials are required: Sterile gauze or cotton

WARNING

For in vitro diagnostic use ONLY

Read the package insert completely before use. It is very important that the correct procedure is followed. Fail to add the patient sample may lead to a false negative result (i.e. a missed positive).

PRECAUTIONS

1. All the waste and specimen should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.
2. Make sure the test is not expired (EXP Date is indicated on the kit box).
3. Do not use the test if the pouch has been perforated.
4. If micro pipette is used, calibrate it frequently to assure the accuracy of dispensing. Use a different disposal pipette tip for each specimen in order to avoid cross-contaminations.
5. Do not modify the test procedure.
6. Each test is for single use only.
7. Blood that has been chemically treated, heated, diluted, or otherwise modified may result in inaccurate results.
8. Always interpret the results under good light conditions to avoid misreading of the results.
9. Different batch of product components cannot be mixed.
10. If desiccant bag is not present in the pouch, DO NOT USE the test.

11. Use micro pipette or the supplied disposable droppers for transfer of specimens onto the test cassette. When using micro pipette, the volume of specimen added is 35µL, the volume of diluent buffer added is 50µL.
12. Always add accurate volume of specimen by following the instruction.
13. The test cassette must be used directly after unsealing. It is not allowed to divide it for use.
14. Read the result after 15 minutes but not more than 30 minutes. Interpret the test result before 15 minutes or after 30 minutes may cause false result.

STORAGE

Newscen HIV (1+2) Antibody Rapid Test should be stored at room temperature (4-30 ° C, do not freeze) for 24 months from the date of manufacture. Keep the test cassette in sealed pouch until use. Once you have taken the test cassette out of the pouch, perform the test as early as possible (within 1 hour) to avoid test cassette from becoming moist. Do not use the test beyond the indicated expiration date.
The diluent buffer should be stored at room temperature (4-30°C, do not freeze).

SAMPLE COLLECTION AND TEST PREPARATION

Fingerstick Specimens (Whole Blood)

1. Clean the area to be lanced with an alcohol pad.
2. Squeeze the end of the fingertip and pierce it with a sterile lancet.
3. Wipe away the first drop of blood with sterile gauze or cotton; collect the sample from the second drop.
4. Use dropper to obtain appropriate amount of fresh blood and dispense into the sample well.

Fingerstick whole blood should be used immediately after collection.
Serum/ Plasma specimens: fresh serum or plasma specimen can be used. No special patient preparation required.

Plasma

1. Collect whole blood into a collection tube (containing EDTA, Na-citrate or heparin) by venipuncture.
2. Separate the plasma by centrifugation.

Serum

1. Collect whole blood into a collection tube (containing no anticoagulants) by venipuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.

Any visible particulate matter in the specimen should be removed by centrifugation or filtration. Avoid using of hemolytic, turbid, microorganism contaminated specimens or specimens stored for over 5 days at 4° C. Specimen should be stored frozen at -20° C for maximum 3 months. Avoid specimen deterioration by multiple freeze-thaw cycles.

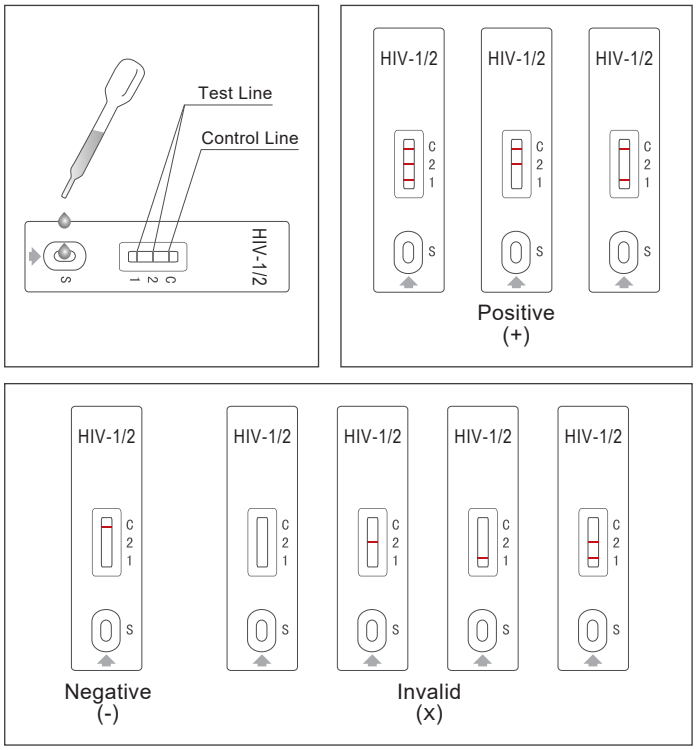
Venous Whole Blood

Venous whole blood can be used immediately after collection or stored up to 4 days at 2-8°C.

ASSAY PROCEDURE

1. Place the test cassette on flat surface. Before unseal the pouch, allow the test cassette to reach room temperature (4-30°C). Use it immediately once unsealed.
2. Open the pouch and add 1 drop (30-40µL) of specimen into the sample well (S).
3. When the specimen is completely absorbed, slowly add 1 drop (45-55µL) of diluent buffer vertically into the sample well (S).
4. Avoid dropping specimen or diluent buffer in the observation window.
5. Do not allow the diluent buffer bottle touch the sample well when dropping the diluent buffer so as to prevent the cross contamination with the specimen.
6. Observe the result between 15-30 minutes after the diluent buffer added.

INTERPRETATION OF RESULTS



Note: 'C' – Control line; '1' – HIV-1 Test line; '2' – HIV-2 Test line

1. ***Negative:*** No red lines appear within 30 minutes in the test zone (1 and 2), only a red line in the control zone (C), which indicates that no antibodies to HIV1+2 have been detected with this test. However, this does not exclude the possibility from infection with HIV.
2. ***Positive:*** One red line in the control zone (C) and one or two red visible lines of any intensity in the test zone (1 and 2). This indicates the specimen contains HIV-1 and/ or HIV-2 antibodies.
3. ***Invalid:*** No red lines appear in the control zone (C), regardless of whether there is a red line in the test zone (1 and 2), indicating that the test is invalid. Discard the test cassette and perform with new cassette.

Built-In Control

Newscen HIV (1+2) Antibody Rapid Test has a built-in procedural control that demonstrates assay validity. A red line appeared on the control zone (C) indicates that the test runs correctly.

LIMITATION

1. The test is intended for qualitative detection of antibodies to HIV.
2. Negative results do not exclude the possibility of HIV exposure or infection. Infection through recent exposure (seroconversion) to HIV, or late AIDS may not be detectable.

3. The positive result obtained with Newscen HIV (1+2) Antibody Rapid Test alone cannot be the final diagnosis of HIV. Any positive result must be interpreted in conjunction with the patient clinical history and another laboratory testing results. Follow-up and supplementary testing of all positive specimens with other tests is required to confirm any reactive result.
4. Newscen HIV (1+2) Antibody Rapid Test does not differentiate between recognition of HIV-1 antibodies and HIV-2 antibodies.
5. Newscen HIV (1+2) Antibody Rapid Test is a qualitative assay and the results cannot be used to measure concentration of antibodies.

PERFORMANCE CHARACTERISTICS

Specificity

A total of 1900 specimens including serum/ plasma and whole blood from vein were tested by Newscen HIV (1+2) Antibody Rapid Test (Table 2).

Table 2

Population	No. of specimens tested	Newscen HIV (1+2) Antibody Rapid Test		Specificity
		Negative	Positive	
Blood donor	1000	1000	0	100%
Whole blood donation	500	500	0	100%
Hospitalized patient specimens	200	197	3	98.5%
Pregnant Women	200	199	1	99.5%
Total	1900	1896	4	99.79%

A total of 100 potentially cross-reacting substances were tested in clinical institutions, the results are presented in Table 3.

Table 3

Potentially cross-reacting substances	No. of specimens tested	Newscen HIV (1+2) Antibody Rapid Test	
		Negative	Positive
Anti-HBs positive	10	10	0
Anti-HBc positive	20	20	0
Anti-HCV positive	15	15	0
Anti-HTLV I/II positive	10	10	0
Anti-HEV positive	10	10	0
Rheumatoid factor positive	10	10	0
CMV Ab positive	5	5	0
EBV Ab positive	5	5	0
Malaria positive	5	5	0
Syphilis positive	5	5	0
Herpes positive	5	5	0
Total	100	100	0

A total of 220 potentially interfering substances were tested in R&D laboratory, the results are presented in Table 4.

Table 4

Potentially interfering substances	No. of specimens tested	Newscen HIV (1+2) Antibody Rapid Test	
		Negative	Positive
Anti-TB positive	20	20	0
HAV-IgM positive	20	20	0
HBsAg positive	20	20	0
Anti-HBs positive	20	20	0
Anti-HCV positive	20	20	0
Anti-TP positive	20	20	0
Rheumatoid factor positive	20	20	0
AFP positive (>20ng/mL)	20	20	0
Triglyceride	20	20	0
Bilirubin	20	20	0
Hemoglobin	20	20	0
Total	220	220	0

Sensitivity

A total of 500 HIV-1 and HIV-2 antibody positive specimens were tested by Newscen HIV (1+2) Antibody Rapid Test (Table 5).

Table 5

Population	No. of specimens tested	Newscen HIV (1+2) Antibody Rapid Test		Sensitivity
		Positive	Negative	
HIV-1Ab positive specimens	360	360	0	100%
non-B subtypes HIV-1 Ab positive specimens	40	40	0	100%
HIV-2 Ab positive specimens	100	100	0	100%
Total	500	500	0	100%

A total of 40 HIV-1 Non-B Subtypes positive specimens (in Table 5) were tested by Newscen HIV (1+2) Antibody Rapid Test, the results are presented in Table 6.

Table 6

HIV Subtype	No. of specimens tested	Newscen HIV (1+2) Antibody Rapid Test
A, A1, A2	3	3
C	3	3
CRF01_AE	3	3
CRF02_AG	3	3
CRF06_cpx	3	3
CRF36_cpx	3	3
D	3	3
F(F1, F2)	4	4
G	3	3
H	3	3
J	3	3
K	3	3
Group O	3	3

A total of 100 paired HIV-1 antibody positive whole blood from vein and plasma specimens were tested by Newscen HIV (1+2) Antibody Rapid Test. (Table 7)

Table 7

Population	No. of specimens tested	Newscen HIV (1+2) Antibody Rapid Test		Sensitivity
		Positive	Negative	
HIV-1 Ab positive whole blood	100	100	0	100%
HIV-1 Ab positive plasma*	100	100	0	100%

*The 100 HIV-1 Ab positive plasma are included in the HIV-1 Ab positive plasma in Table 5.

Seroconversion panels

The sensitivity was evaluated on 31 commercially available

seroconversion panels in institutions ITP and PEI. Overall the Newscen HIV (1+2) Antibody Rapid Test detected 74 out of the 233 seroconversion panel members. This indicates that the Newscen HIV (1+2) Antibody Rapid Test meet the criteria of the CTS (2009/886/EC) of the IVD Directive (98/79/EC) for seroconversion sensitivity.

Anti-coagulants

25 negative donor samples for serum/ plasma (EDTA/ heparin/ Na-citrate) equivalence were tested in a clinical institution: all samples yielded a negative result in the Newscen HIV (1+2) Antibody Rapid Test (Table 8).

Table 8

Newscen HIV (1+2) Antibody Rapid Test	serum	EDTA plasma	Heparin plasma	Na-citrate plasma
Positive	0	0	0	0
Negative	25	25	25	25

25 negative donor samples, spiked with HIV antibodies (20 samples were spiked with an anti-HIV-1 antibody positive sample and 5 samples were spiked with an anti-HIV-2 antibody positive sample), for serum/ plasma (EDTA/ heparin/ Na-citrate) equivalence were tested: all samples yielded a positive result in Newscen HIV (1+2) Antibody Rapid Test (Table 9).

Table 9

Newscen HIV (1+2) Antibody Rapid Test	serum	EDTA plasma	Heparin plasma	Na-citrate plasma
Spike with Anti-HIV-1 positive sample				
Positive	20	20	20	20
Negative	0	0	0	0
Spike with Anti-HIV-2 positive sample				
Positive	5	5	5	5
Negative	0	0	0	0

Consistency of fingerstick whole blood and venous whole blood

A total of 55 positive blood specimens and 65 negative blood specimens were tested by Newscen HIV (1+2) Antibody Rapid Test in two laboratories test centers. Collect the fingerstick and venous blood specimen from the same patient at the same time. (Table 10)

Table 10

Results of fingerstick whole blood	Results of venous whole blood		Total
	Positive	Negative	
Positive	55	0	55
Negative	0	65	65
Total	55	65	120

REFERENCE

1. Essex, M. (1999) Human immunodeficiency viruses in the developing world. Adv Virus Res 53: 71-88.
2. CDC. Revised Guidelines for HIV Counseling, Testing and Referral and Revised Recommendations for HIV screening of Pregnant Women. MMWR 2001; 50(19); 32-35.
3. 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.
4. Coffin J, Haase A, Levy JA, et al: What to call the AIDS virus? Nature 321: 10, 1986.
5. Popovic, M., et al: Detection isolation and continuous production of Cytopathic Retroviruses (HTLV.III) from patients with AIDS and pre-AIDS. Science 1984; 224: 497.
6. Carison, J. R. et al: AIDS serology testing in low and high risk groups.JAMA1985; 253: 3405.
7. Centers for Disease control, Update on Acquired Immune Deficiency Syndrome (AIDS) MMWR 1982; 31: 507.
8. CDC. Universal precautions for preventation of transmission of human immunodeficiency virus, hepatitis B virus and other blood-borne pathogens in health-care settings. MMWR 1988; 37(24): 377-388.
9. Gallo, RC, et al: Frequent detection and isolation of Cytopathic Retroviruses (HTLV.III) from patients with AIDS and a risk for AIDS. Science.1984; 224: 500.

INDEX OF SYMBOLS

	Do not re-use
REF	Catalogue number
IVD	For In Vitro Diagnostic medical device
	Use by date
	Date of manufacture
4C 30C	Temperature limitation
	Consult instructions for use
EC REP	Authorized Representative in the European Community
LOT	Batch code
Σ n	Contains sufficient for < n > tests
CE 0123	CE Mark
	Manufacturer

Product disclaimer: This product has been manufactured under strict GMP regulation to ensure the diagnostic accuracy of the test. It is out of control of the manufacture when the test is performed in diverse environment and by diverse group of individuals that may affect the results to a certain degree.

Note: The manufacturer, the distributor, or its associates will not be liable for any losses, claims, liability, costs or damages, whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether a positive or negative by use of this product.

NEWSCEN COAST BIO-PHARMACEUTICAL CO., LTD.
No. 65, 6th Street, Tianjin TEDA, 300457, Tianjin, PEOPLE'S REPUBLIC OF CHINA
Tel: +86(22)25321648
Fax: +86(22)25328062
Web(CN): www.newscen.com
Web(EN): www.newscenbiotech.com
E-mail: export@newscen.com

Wellkang Ltd (www.CE-marking.eu)
Enterprise Hub, NW Business Complex, 1 Beraghmore Road,
Derry, BT48 8SE, Northern Ireland, UK