

IVD Version: A/4 Revision Date: 2025-06-04

REF HIV_v-29200111000 HIV_v-29200201000

HIV_v-29200501000 HIV_v-29202511000 HIV_v-29204017000

HIV (1+2) Antibody Rapid Test

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

The instruction must be read carefully and completely prior to the use of HIV (1+2) Antibody Rapid Test. Instruction must be followed carefully. If directions are not followed exactly, inaccurate test result may occur. Please contact manufacturer for more printed copies or electronic version of IFU. See the diagram on back page for quick reference.

INTENDED USE

HIV (1+2) Antibody Rapid Test is a single use, in vitro diagnostic medical device. It is a rapid immunoassay for the qualitative detection of antibodies specific to Human Immunodeficiency Virus type 1 and 2 (HIV-1/2) in human serum, plasma or whole blood collected from vein or fingertip. This test is intended as an aid in the diagnosis of HIV infection in patients with clinical signs and symptoms and patients at risk of HIV infection. HIV (1+2) Antibody Rapid Test is intended for professional laboratory use only. This test is neither automated nor suitable for self-testing, blood screening or near patient use.

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 HIV-1 and HIV-2 specific recombinant antigens, which have been conjugated with colloidal gold particles. 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) suggest 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.

KIT COMPONENTS

Components	Quantity (pcs)				
	1 Test (HIV _v - 292001 11000)	2 Tests (HIV _v - 29200201 000)	5 Tests (HIV _v - 29200501 000)	25 Tests (HIV _v - 29202511 000)	40 Tests (HIV _v - 29204017 000)
Test cassette	1	2	5	25	40
Desiccant	1	2	5	25	40
Dropper	1	2	5	25	40
Diluent buffer	1×1mL	1×1mL	1×1mL	2×5mL	2×5mL
Sterile lancet	1	2	5	Not provided	Not provided
Alcohol pad	1	2	5	Not provided	Not provided
Instruction for use	1	1	1	1	1

Table 1 Manufacturer information of purchased components

Sterile lancet CE 0123		Ningbo Medsun Medical Co., Ltd. No.55 Jinxi Road, Zhenhai 315221 Ningbo P.R. China	EC REP		Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80,20537 Hamburg, GERMANY
		Lights Medical Manufacture Co., Ltd. No. 19, Quanda Road, Wuqing Development Area, Tianjin 301700, P.R. China.			WellKang Ltd The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland
Alcohol pad CE 0197			EC REP		

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch
- Blood collection devices, for the testing of venous whole blood, serum or plasma
- Biohazard disposal container
- Disposable gloves
- Sterile gauze or cotton

For fingertick samples, the following materials are required:

- Alcohol pad
- Sterile lancet

STORAGE

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

The diluent buffer should be stored at 4-30 C (do not freeze) for 24 months from the date of manufacture. It will not be affected for use before the expiry date, if the diluent bottle is opened no more than 40 times.

WARNING AND PRECAUTIONS

- For in vitro diagnostic use ONLY.
- The instruction must be read carefully to obtain an accurate result.
- All the waste and specimen should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.
- Make sure the test is not expired (EXP Date is indicated on the kit box).
- Do not use the test if the pouch has been damaged.
- If pipette is used, calibrate it frequently to assure the accuracy of dispensing. Change a new disposal pipette tip for each specimen to avoid cross-contaminations.
- Do not modify the test procedure.
- The diluent buffer is reusable, the other kit components are for single use only.
- Diluent buffer and test cassette from different batches of the kit cannot be mixed.
- Blood that has been chemically treated, heated, diluted or modified may result in inaccurate results.
- The diluent buffer contains sodium azide as a preservative (≤0.1%). Avoid skin contact with this reagent. Sodium azide may react with lead and copper in plumbing and form highly explosive metal oxides^[1]. Flush the plumbing with a large quantity of water if solutions containing azide are disposed in the sink.
- If desiccant bag is not present in the pouch, DO NOT USE the test.
- Use pipette or the provided droppers for transfer of specimens onto the test cassette. Always add accurate volume of specimen by following the instruction.
- Read the result after 15 minutes but not longer than 30 minutes. Interpret the test result before 15 minutes or after 30 minutes may cause false result.
- The recommended temperature for testing is 15-30 C and the storage temperature is 4-30 C. Temperature beyond the range may affect the product performance, it is recommended to strictly follow the required temperature.

SAMPLE COLLECTION AND TEST PREPARATION

Fingerstick Whole Blood:

- Clean the finger with alcohol pad and leave it to dry.
- Puncture the side of the finger tip with a sterile lancet.
- Gently press around the bleeding point. Wipe away the first drop of blood, collect the sample from the second drop.
- Absorb sufficient fresh blood with the dropper provided.

Fingerstick whole blood should be used immediately after collection.

Plasma:

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

Serum:

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

Serum/plasma specimens should be tested immediately after collection. Do not leave the specimens at room temperature (15-30 C) for prolonged periods. If not tested immediately, the serum/plasma specimens should be stored at 2-8 C no more than 5 days or frozen at -20 C for maximum 12 weeks. Multiple freeze-thaw cycles should be avoided (3 times at most).

Venous whole blood (EDTA, Na-citrate or heparin as anticoagulants) can be used immediately after collection or stored up to 4 days at 2-8 C.

Note: Any visible particulate matter in the specimen should be removed by centrifugation or filtration. Avoid using of hemolytic, turbid, microorganism contaminated specimens. Specimens stored at 2-8 C must be brought to room temperature before use. Frozen specimens must be completely thawed and mixed well prior to testing.

ASSAY PROCEDURE

- Allow the test cassette to reach temperature at 15-30 C before unsealing the pouch. Place the test cassette on a flat, clean and dry surface.
- Once the test cassette is removed from the pouch, the test procedure should be performed within 1 hour.
- When using dropper, add 1 drop (30-40μL) of specimen into the sample well (S).
- After adding the specimen, screw off the cap on top of the buffer bottle, slowly add 1 drop (45-55μL) of diluent buffer vertically into the sample well (S).
- When using pipette, the volume of specimen added is 35μL, the volume of diluent buffer added is 50μL.
- Avoid dropping specimen or diluent buffer in the result window.
- Do not allow the tip of diluent buffer bottle to touch the sample well, as it may contaminate the diluent buffer.
- Observe the result between 15-30 minutes after the diluent buffer is added.

INTERPRETATION OF RESULTS

- Negative:** No red lines appear 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.
- Positive:** One red line in the control zone (C) and one or two red lines in the test zone (1 and/ or 2). No matter the test line is strong or faint, it indicates the specimen contains HIV-1 and/ or HIV-2 antibodies.
- Invalid:** No red line appears in the control zone (C), regardless of whether there is one red line or two red lines in the test zone (1 and/ or 2), indicating that the test is invalid. Discard the test cassette and retest with a new cassette.

Built-In Control

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

LIMITATION

- The test is intended for qualitative detection of antibodies to HIV.
- 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.^[2]
- The positive result obtained with 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.^[3]
- HIV (1+2) Antibody Rapid Test cannot be used for genotyping diagnosis.^[4] The presence of any line in the test zone indicates a positive result.
- HIV (1+2) Antibody Rapid Test cannot be used to measure concentration of antibodies.

PERFORMANCE CHARACTERISTICS

Sensitivity

A total of 500 specimens including HIV-1, HIV-2, whole blood/ plasma couples and non-B-subtypes positive samples (subtype: A, A1, A2, C, CRF01_AE, CRF02_AG, CRF06_cpx, CRF36_cpx, D, F1, F2, G, H, G, K, Group O) were tested by HIV (1+2) Antibody Rapid Test. The sensitivity was 100%. For details see table 2.

Table 2 Results obtained on anti-HIV positive samples

Specimens	n	HIV (1+2) Antibody Rapid Test		Sensitivity
		Positive	Negative	
HIV-1 Ab positive (serum/plasma)	260	260	0	100%
HIV-1 Ab positive (whole blood/plasma couples)	100	100	0	100%
non-B-subtypes HIV-1 Ab positive (plasma)	40	40	0	100%
HIV-2 Ab positive (serum/plasma)	100	100	0	100%
Total	500	500	0	100%

Seroconversion panels

31 commercially available seroconversion panels were evaluated. Overall, the HIV (1+2) Antibody Rapid Test detected 74 out of the 233 seroconversion panel members, representing a higher sensitivity compared with the reference tests which detected 70 positive cases.

Specificity

A total of 1700 specimens including unselected blood donors serum/ plasma, whole blood from vein and hospitalized patient samples were tested by HIV (1+2) Antibody Rapid Test. The specificity was 99.82%. For details see table 3.

Table 3 Results obtained on anti-HIV negative samples

Population	n	HIV (1+2) Antibody Rapid Test		Specificity
		Negative	Positive	
Blood donor	1000	1000	0	100%
Whole blood donation	500	500	0	100%
Hospitalized patient	200	197	3	98.5%
Total	1700	1697	3	99.82%

Cross-reactivity

A total of 320 specimens, including those from pregnant women and potentially cross reacting substances, were evaluated by HIV (1+2) Antibody Rapid Test. For details see table 4.

Table 4 Cross reacting substances

Population	n	HIV (1+2) Antibody Rapid Test	
		Negative	Positive
Pregnant Women	200	199	1
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
Anti- <i>E. coli</i> positive	20	20	0
Total	320	319	1

25 negative donor samples for serum/ plasma (EDTA/ heparin/ Na-citrate) were tested: all samples obtained negative test results independent of the sample matrix. 25 negative donor samples, spiked with HIV-1 and HIV-2 antibodies, for serum/ plasma (EDTA/ heparin/ Na-citrate) were tested: all samples obtained positive test results.

Endogenous interfering substance

A total of 120 samples with endogenous interfering substances were tested in R&D laboratory, the results showed that these compounds had no effect on specificity. For details see table 5.

Table 5 Endogenous interfering substances

Specimens	n	Information/ Concentration	HIV (1+2) Antibody Rapid Test	
			Negative	Positive
RF	20	≤296 IU/mL	20	0
Late pregnancy serum	20	≤97521 mIU/mL	20	0
High AFP serum	20	≤321.66 ng/mL	20	0
Hyperlipemia	20	≤8.73 mg/dL	20	0
High bilirubin	20	≤159.3 μmol/L	20	0
Haemolysin	20	≤6.78 mg/mL	20	0
Total	120	/	120	0

Exogenous interfering substance

The details of potentially exogenous interfering substances were mentioned in the following table 6. These potentially interfering conditions do not affect the performance of the HIV (1+2) Antibody Rapid Test.

Table 6 Exogenous interfering substances

Anticoagulant/ preservative	Concentration	Drugs	Concentration
Heparin	30IU/ml	Abacavir	16.4 μg/mL
Sodium citrate	10.9 mmol/L	Lamivudine	6.8 μg/mL
EDTA	0.3%	Tipranavir	3.7 μg/mL
Sodium azide	0.1%	Eavirenz	15.7 μg/mL

Reproducibility

HIV (1+2) antibody rapid test was found to be consistent and stable when it was tested by 10 operators, at 5 separate sites, 5 times a day, in 5 continuous days, testing 3 different lots. The overall reproducibility was 100%.

Applicable sample consistency

100 cases of whole blood, serum and plasma from the same patient were tested by HIV (1+2) antibody rapid test, 100% consistency was achieved. Fingertick and venous blood specimen from the same patient as total of 55 positive and 65 negative were tested, the total coincidence rate was 100%.

REFERENCE

- Hagenbuch J P. Opportunities and limits of the use of azides in industrial production. Implementation of safety measures[J]. *Chimia*, 2003, 57(12): 773-773.
- Kabir M A, Zilouchian H, Caputi M, et al. Advances in HIV diagnosis and monitoring[J]. *Critical reviews in biotechnology*, 2020, 40(5): 623-638.
- Drain P K, Rousseau C. Point-of-care diagnostics: extending the laboratory network to reach the last mile[J]. *Current Opinion in HIV and AIDS*, 2017, 12(2): 175-181.
- Guiraud V, Bocobza J, Desmonet M, et al. Are confirmatory assays reliable for HIV-1/HIV-2 infection differentiation? A multicenter study[J]. *Journal of Clinical Microbiology*, 2023, 61(8): e00619-23.

INDEX OF SYMBOLS

	Do not re-use		Consult instructions for use
	Catalogue number		Authorized Representative in the European Community
	For In Vitro Diagnostic medical device		Contains sufficient for < n > tests
	Use by date		Batch code
	Date of manufacture		CE Mark
	Temperature limitation		Manufacturer
	Unique device identifier		Importer

Product disclaimer: This product meets the criteria of ISO9001:2015 and ISO13485:2016 to ensure the quality standard. It is out of control of the manufacturer when the test is performed in diverse environment and by diverse group of individuals that may affect the results to a certain degree. 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. **Note:** Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established. Information about the Summary of safety and performance can be found at the EUDAMED website.

NEWS-SCEN COAST BIO-PHARMACEUTICAL CO., LTD.

No. 65, 6th Street, Tianjin TEDA, 300457, Tianjin, PEOPLE'S REPUBLIC OF CHINA

Tel: +86(22)25321648

E-mail: export@newsccn.com

Web: www. newsccn.com (CN)

Web: www. newsccnbiotech.com (EN)

WellKang Ltd

Enterprise Hub, NW Business Complex, 1 Beraghmore Road, Derry, BT48 8SE,

Northern Ireland, UK.

HIV (1+2) Antibody Rapid Test

HIV₃-29200111000 HIV₃-29200201000 HIV₃-29200501000 HIV₃-29202511000 HIV₃-29204017000

Kit Components

The kit components of HIV₃-29200111000, HIV₃-29200201000, HIV₃-29200501000 are as below.


Test cassette (individually pouched, with 1 desiccant and 1 dropper)



Diluent buffer



Sterile lancet



Alcohol pad



Instruction for use

The kit components of HIV₃-29202511000, HIV₃-29204017000 are as below.


Test cassette (individually pouched, with 1 desiccant and 1 dropper)



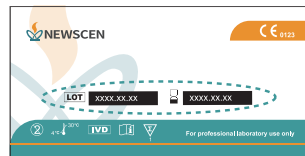
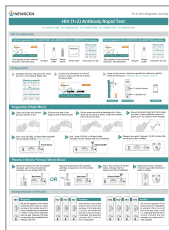
Diluent buffer



Instruction for use

Preparation

- Carefully read the instructions for using the HIV (1+2) Antibody Rapid Test.
- Confirm the information on the foil pouch to make sure the kit is within the expiry date.
- Open the foil pouch, check the cassette, desiccant and the dropper inside the foil pouch. **Perform the test within 1 hour**



Foil pouch



Dropper



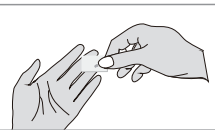
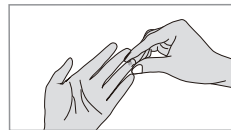
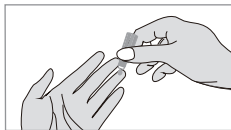
Test cassette



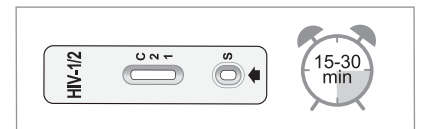
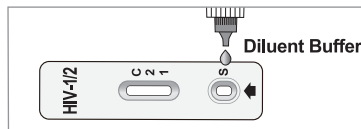
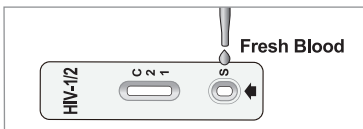
Desiccant

Fingerstick Whole Blood

- Clean the finger with alcohol pad and leave it to dry.
- Puncture the side of the finger tip with a sterile lancet.
- Gently press around the bleeding point. Wipe away the first drop of blood, collect the sample from the second drop.
- Absorb sufficient fresh blood with the dropper provided.

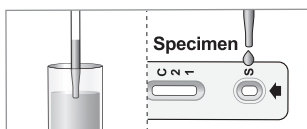


- Add 1 drop (30-40µL) of fresh blood vertically into the sample well (S). **Do not tilt**
- Add 1 drop (45-55µL) of diluent buffer vertically into the sample well (S).
- Observe the result between 15-30 minutes after the diluent buffer is added.

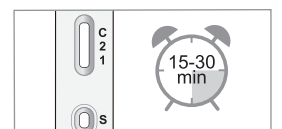
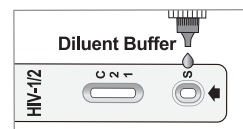
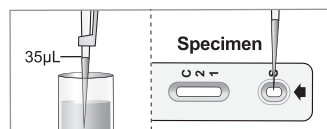


Plasma / Serum / Venous Whole Blood

- Absorb the specimen with the dropper provided, add 1 drop of specimen vertically into the sample well (S).
- Absorb the specimen with a pipette, add 35µL of specimen into the sample well (S).
- Add 1 drop or 50µL of diluent buffer vertically into the sample well (S).
- Observe the result between 15-30 minutes after the diluent buffer is added.

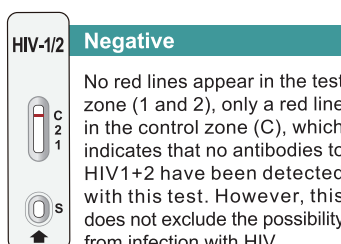


OR



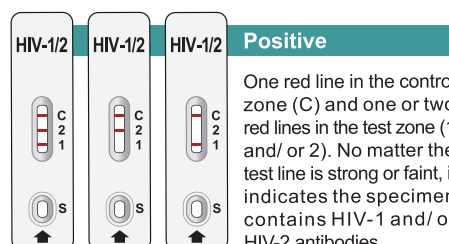
Interpretation of Results

HIV-1/2 Negative



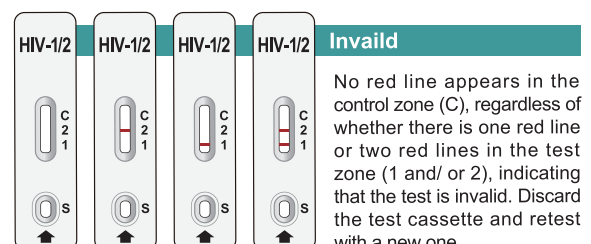
No red lines appear in the test zone (1 and 2), only a red line in the control zone (C), which indicates that no antibodies to HIV1+2 have been detected with this test. However, this does not exclude the possibility from infection with HIV.

HIV-1/2 Positive



One red line in the control zone (C) and one or two red lines in the test zone (1 and/or 2). No matter the test line is strong or faint, it indicates the specimen contains HIV-1 and/or HIV-2 antibodies.

HIV-1/2 Invalid



No red line appears in the control zone (C), regardless of whether there is one red line or two red lines in the test zone (1 and/or 2), indicating that the test is invalid. Discard the test cassette and retest with a new one.