01.05.03.916-170203

REF ITP02121-TC40
ITP02122-TC10
ITP02122-TC40

ADVANCED QUALITY™

Швидкий тест для визначення антитіл до ВІЛ 1/2

Діагностичний набір для визначення антитіл до вірусу імунодефіциту людини (колоїдне золото) ***(цільна кров/сироватка/плазма)***

Умовні позначення, що використовуються:

REF Номер за каталогом

IVD Медичний виріб для діагностики In Vitro

Виробник

CE маркування

2°C 30°C Зберігати при 2-30℃

Термін придатності

Не використовуйте повторно

УВАГА

Ознайомтеся з інструкцією з використання

Σ 10 Містить 10 тестів

Σ 40 Містить 40 тестів

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332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, 361022, P.R. China

EC REP **Qarad b.v.b.a.**
Cipalstraat 3, B-2440 Geel, Belgium

CE 0123

Dhfihggb	10 lkl (dlghf ITP02122-TC10)	40 lkl (dlghf ITP02122-TC40)	40 lkl (dlghf
LkldZjldZ	10	40	40
leZkldhZildZ	10	40	40
JhaqbggbdajZadZ	10x 05fene	4x 2fene	4x 2fene
EZgplbhghjZahhh bdhjbklZggy	10	40	ggZZlvky
Kibjlhkjldb	10	40	ggZZlvky
1gkljmdpyabdhjbklZggy	1	1	1

Примітка: інформація про ланцети одноразового використання та спиртові серветки

Аксесуар	Виробник	Уповноважений представник	CE знак
Ланцети одноразового використання	SteriLance Medical (Suzhou) Inc. No.68 Litanghe Road, Xiangcheng, Suzhou, China	EMERGO EUROPE Molenstraat 15, 2513 BH, The Hague, The Netherlands	CE 0197
пиртов серветки			CE

KdeZjhaqbggbdZ

KH_2PO_4	0.00082г/мл
K_2HPO_4	0.01344г/мл
BSA	20%
NaN_3	0.02%

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch
- Blood collection devices
- Biohazard disposal container
- Disposable gloves

STORAGE AND STABILITY

The kit has a 24 month shelf-life from the date of manufacture. Store the unused kits at 2°C - 30°C. If stored refrigerated, ensure that the sealed pouch is brought to room temperature (10°C -30°C) before opening for testing. The sample diluent should be consumed within 8 weeks.

WARNINGS AND PRECAUTIONS

1. All positive results must be confirmed by an alternate method.
2. Treat all specimens and reagents as potentially infectious materials. Wear gloves and protective clothing while operation. The waste disposal of potentially infectious materials should subject to appropriate biosafety practices.
3. Do not use kit materials beyond their expiration dates.
4. Do not interchange reagents from one kit lot to another.
5. Do not re-use the tests or any single use accessories (test card, plastic dropper, Sample diluents, Disposable Safety Lancets, Disposable Swabs, desiccant).
6. Do not use the test if the foil pouch is damaged.
7. Do not use the Disposable Safety Lancets if the cap is already pulled off.
8. Do not use the Disposable Swabs if the pouch is damaged.

SAMPLE COLLECTION AND STORAGE

Fingerstick whole blood

1. Using the Disposable Swabs (antiseptic alcohol swab). Clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad. Using the Safety Lancets (for the provided Disposable Safety Lancets: twist off the protective cap, then pull the cap), prick the skin on the side of fingertip. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed. Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
2. Pick up an unused specimen collection disposable dropper to collect the drop of blood.

Venous whole blood

1. Using standard venous phlebotomy procedure, collect a whole blood sample using a tube containing any of the following anticoagulants: EDTA, heparin, or sodium citrate. Other anticoagulants have not been tested and may give an incorrect result. If the specimens are not tested at the time of collection, the whole blood can be stored at 2°C -8°C for 3 days. Before testing, bring the specimens to room temperature and mix the blood tube gently by inversion several times to ensure a homogeneous sample.
2. Pick up an unused specimen collection disposable dropper to collect the drop of blood.

Serum or plasma

1. SERUM

Using the standard venous phlebotomy procedure collect a whole blood sample using a tube **NOT** containing any of the following anticoagulants: EDTA, heparin, or sodium citrate. Leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.

2. PLASMA

Using the standard venous phlebotomy procedure collect a whole blood sample using a

tube containing any of the following anticoagulants: EDTA, heparin, or sodium citrate. And then centrifuge blood to get a plasma specimen.

Note:

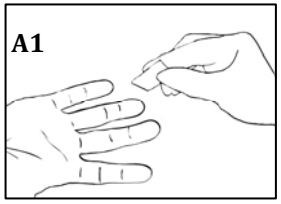
1. If serum or plasma specimens are not tested immediately, they should be refrigerated at 2°C -8°C. For storage period longer than 7days, freezing is recommended. Please bring the specimens to room temperature before testing.
2. Serum or plasma specimens containing a precipitate may yield inconsistent test result. Such specimens must be clarified before testing.

ASSAY PROCEDURE

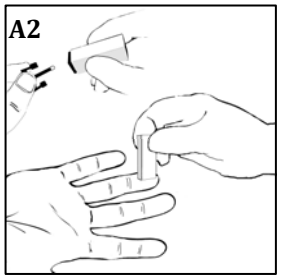
Do not open the pouch until you are ready to perform a test, and the single-use test is suggested to be used under low environment humidity (RH≤70%) within 1 hour.

Test procedure for Fingerstick whole blood

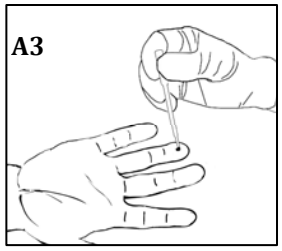
1. Leave all reagents and specimens to reach room temperature (10-30℃).
2. Take out test card from aluminum foil pouch and put it on a clean and dry surface.
3. Identify the test card for each specimen or control.
4. Rub the finger to stimulate blood flow, clean the subject's finger with the Disposable Swabs (antiseptic alcohol swab) and leave the finger to dry in the air or wipe dry with a sterile gauze (Figure A1).



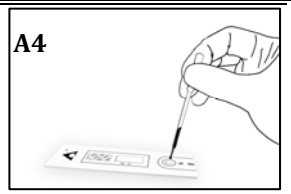
5. Prick the skin on the side of fingertip with the Safety Lancets (for the provided Disposable Safety Lancets: twist off the protective cap, then pull the cap), and keep it face down, lightly press the bleeding point (avoid excessive bleeding). Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form (Figure A2).



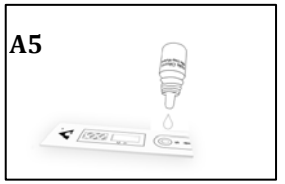
6. Collect blood specimen with the Plastic Dropper provided (Figure A3).



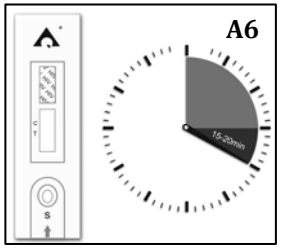
7. Add 30µl (or 1 drop by the provided Plastic Dropper) of fingerstick whole blood to the Sample Port (Port S) on test cassette (Figure A4).



8. Then add 1 drop (50µl) of sample diluent to the Sample Port (Port S) immediately (Figure A5).

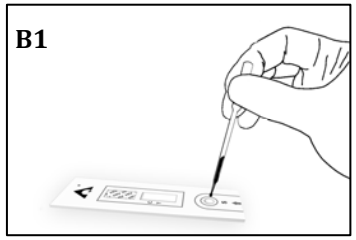


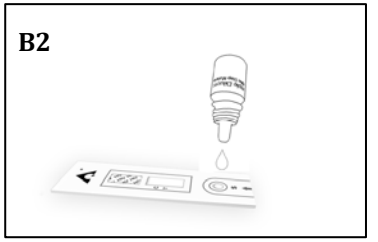
9. Wait for at least 15 minutes (and 20 minutes at most) to read the result (Figure A6).

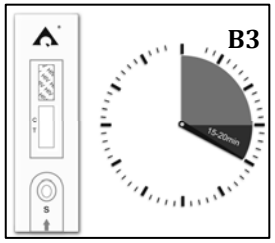


Test procedure for Venous whole blood

1. Leave all reagents and specimen to reach room temperature (10-30℃).
2. Take test card out of aluminum foil pouch and put it on a clean and dry surface.
3. Identify the test card for each specimen or control.
4. Add 30µl (or 1 drop by the provided Plastic Dropper) of venous whole blood to the Sample Port (Port S) on test card (Figure B1)
5. Then add 1 drop (50µl) of sample diluent to the Sample Port (Port S) immediately (Figure B2)
6. Wait for at least 15 minutes (and 20 minutes at most) to read the result. (Figure B3).

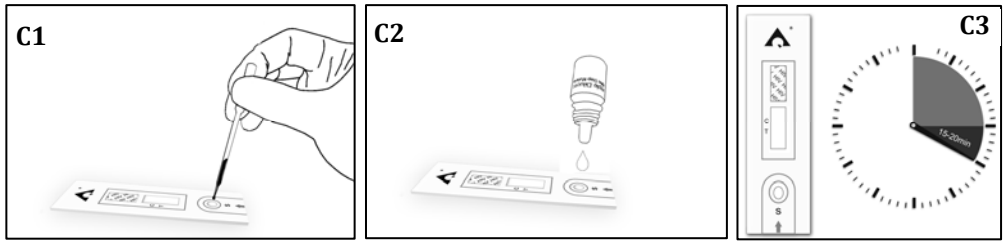






Test procedure for Serum or plasma

1. Leave all reagents and specimen to reach room temperature (10-30℃).
2. Take test card out of aluminum foil pouch and put it on a clean and dry surface.
3. Identify the test card for each specimen or control.
4. Add 30μl (or 1 drop by the provided Plastic Dropper) of serum or plasma to the Sample Port (Port S) on test card (Figure C1).
5. Then add 1 drop (50μl) of sample diluent to the Sample Port (Port S) immediately (Figure C2).
6. Wait for at least 15 minutes (and 20 minutes at most) to read the result (Figure C3).

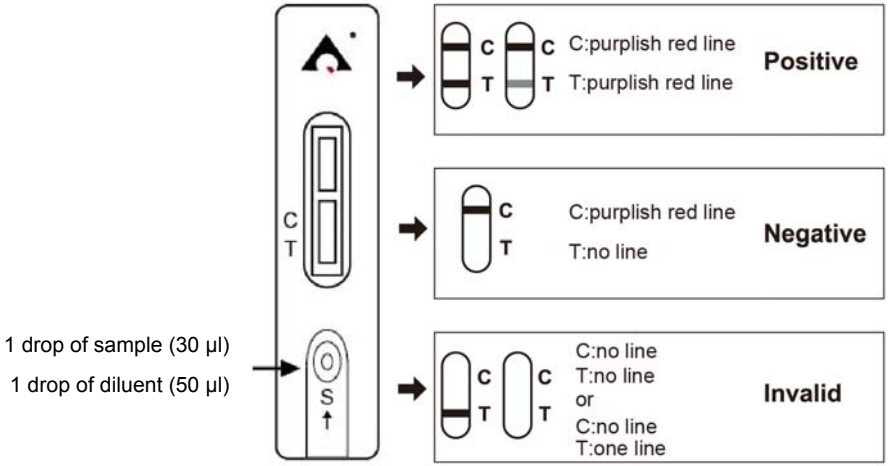


⚠ **Caution: Always apply specimen with a new and clean Plastic Dropper or pipette tip, to avoid cross contamination**

Notes:

1. *A positive result may be interpreted early, however read any negative at 15 minutes to ensure sample is negative and not a low concentration of the anti-HIV antibody. Do not interpret the result after 20 minutes.*
2. *The positive results could appear as soon as 1 minute for a sample with high levels of HIV antibodies.*
3. *No test provides absolute assurance that a specimen does not contain low levels of HIV antigen and/or antibodies to HIV-1/2 such as those present at a very early stage of infection. A negative result does not preclude the possibility of exposure to or infection with HIV-1 or HIV-2 viruses.*

INTERPRETATION OF TEST RESULTS



1. *Positive:* Both purplish red test band and purplish red control band appear on the membrane.

2. *Negative:* Only the purplish red control band appears on the membrane. The absence of a test band indicates a negative result.

3. *Invalid:* There should always be a purplish red control band in the control region regardless of test result. If control band is not seen, the test is considered invalid. Repeat the test using a new test device.

Note: It is normal to have a slightly lightened control band with very strong positive samples as long as it is distinctly visible.

PERFORMANCE CHARACTERISTICS

The performance of the Advanced Quality™ ONE STEP Anti-HIV (1&2) Test has been evaluated by testing specimens from random blood donors, from patients with HIV infection and commercial seroconversion panels. The performance evaluations were conducted in to show compliance to the Common Technical Specifications including studies performed in-house and in two external laboratories in Europe.

1. Sensitivity

Table I Performance on HIV positive samples

Types	ONE STEP Anti-HIV (1&2) Test		
	Positive by ONE STEP Anti-HIV (1&2) Test	Total specimens tested	Sensitivity
HIV-1 positive with reference tests	259	260	99.62%

HIV-1 positive from EDTA plasma / whole blood comparison study	100	100	100%
HIV-1 non-B subtype *	40	40	100%
HIV-2	100	100	100%
Total	499	500	99.8%

*Subtypes of A, C, D, F, G, H, J, K, O and CRF AE etc. were included.

The diagnostic sensitivity of ONE STEP Anti-HIV on HIV positive specimens is calculated to be 99.8%. For the specimen lost, further characterization revealed that it was subtype A virus of recent infection close to sero-conversion. And it is lost also by other two CE-marked rapid tests.

Table II. Performance on Sero-conversion panels

Panel ID	Number of reactive panel members / total number of panel members	
	Enzygnost anti-HIV ½ Plus	ONE STEP Anti-HIV (1&2) Test
PRB-914 N	5/5	5/5
PRB-916 P	2/6	2/6
PRB-919 S	2/3	2/3
PRB-924 X	3/8	3/8
PRB-925 Y	2/6	2/6
PRB-926 Z	2/6	2/6
PRB-927 AB	4/5	3/5
PRB-934 AI	2/3	2/3
PRB-942 AR	0/4	0/4
PRB-947 AW	3/4	3/4
PRB-950 AZ	1/4	1/4
PRB-951 BA	1/6	1/6
PRB-952 BB	2/6	2/6
PRB-953 BC	1/4	1/4
PRB-954 BD	0/7	0/7
PRB-955 BE	2/5	1/5
PRB-956 BF	0/5	0/5
PRB-957 BG	1/7	1/7
PRB-958 BH	2/6	2/6
PRB-959 BI	4/7	4/7
Total score	39/107	37/107

The following results were obtained with the ONE STEP Anti-HIV (1&2) Test and with the reference method Enzygnost Anti-HIV ½ Plus. Among the 107 specimens of the sero-conversion panels, 31 samples were defined as “sero-conversion HIV samples”, and all yielded a positive result with the ONE STEP Anti-HIV (1&2) Test; 16 samples were determined as “early seroconversion HIV samples”, and only two were missed compared to the reference.

2. Specificity

Table III. Performance on negative blood donations

blood donor samples	ONE STEP Anti-HIV (1&2) Test		
	Negative	positive	Total
EDTA plasma samples			
Prism HIV combo*	1000	0	1000
Whole blood samples			
Prism HIV combo	1000	0	1000

* Reference test.

Besides, 200 clinical specimens, 200 specimens from pregnant women (including 180 of 1st pregnancy and 20 of 2nd or later pregnancy) were tested; all the results indicated a specificity of 100%.

3. Potential interference

Table IV. Performance on potentially interfering specimens

Interfering specimens	ONE STEP Anti-HIV (1&2) Test		
	Negative	positive	Total

anti-HCV positive	20	0	20
anti-HBsAg positive	20	0	20
anti-HBc positive	20	0	20
anti-HTLV I/II positive	20	0	20
anti-HEV positive	20	0	20
anti-CMV IgM	9	1	10
anti-EBV IgM	10	0	10
Rheumatoid factor	10	0	10
Total	129	1	130

The results showed Specificity on possibly interfering samples of 99.23%.

4. Performance on different types of specimens

Sensitivity and specificity tests above were performed on EDTA plasma samples. Compatibility of EDTA plasma and whole blood specimens can be concluded from above tests, furthermore, The ONE STEP Anti-HIV (1&2) Test can be performed on other specimen types as well: citrate plasma, heparin plasma, serum etc.

Table V. Performance on different types of specimens

ONE STEP Anti-HIV (1&2) Test				
		EDTA plasma samples		
		Negative	positive	Total
Citrate plasma samples	negative	30	0	30
	positive	0	30	30
	total	30	30	60
Heparin plasma samples	negative	30	0	30
	positive	0	30	30
	total	30	30	60
serum samples	negative	30	0	30
	positive	0	30	30
	total	30	30	60

Table VI. Venous whole blood/ Fingerstick whole blood comparison test with HIV-positive &HIV-negative specimens

	HIV positive specimens		**HIV negative specimens**	
	Venous whole blood	Fingerstick whole blood	Venous whole blood	Fingerstick whole blood
Specimens Tested	26	26	25	25
Test negative	0	0	25	25
Test positive	26	26	0	0
Concordance rate	100%	100%	100%	100%

From the above information and Table V, Table VI, it is concluded that ONE STEP Anti-HIV (1&2) Test gives identical test results for specimen type serum, plasma, venous whole blood and fingerstick whole blood.

LIMITATIONS

1. Only samples that are not hemolyzed and that are with good fluidity can be used in this test.
2. Fresh samples are best but refrigerated and frozen samples can also be used after thawing and balancing to the room temperature. However for whole blood, frozen samples cannot be used.
3. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.

BIBLIOGRAPHY

1. Blattner, W., Gallo, R.C. and Temin. H.M. HIV causes AIDS. Science. 241:515, 1988.
2. Curran, J.W., Morgan. W.M., Hardy, A.M., et al. The epidemiology of AIDS: Current status and future prospects. Science 1985; 229:1352:1352-7.

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