REF ITP02152-TC25
ITP02152-TC40
ITP02153-TC10
ITP02153-TC40

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CE 0123

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ADVANCED QUALITY™

ONE STEP Anti-HIV (1&2) Test

Diagnostic Kit for Antibody to Human Immunodeficiency Virus (Colloidal Gold)
(Whole Blood/Serum/Plasma)

For Professional Use Only

Key to symbols used:			
REF	Catalogue Number	Contents	Contents
IVD	In Vitro Diagnostic Medical Device	Test	Test device
	Manufacturer	Tests	Test devices
CE	CE Mark	Dropper	Plastic dropper
2°C 30°C	Store at 2-30℃	Diluent	Sample diluents
	Use-by date	Pack Insert	Package insert
	Do Not Reuse	Safety Lancet	Disposable safety lancet
	CAUTION	Alcohol Swab	Disposable alcohol swab
	Consult Instructions For Use	STERILE R	STERILIZED USING IRRADIATION
Σ 10	Contains Sufficient material for 10 tests		
Σ 25	Contains Sufficient material for 25 tests		
Σ 40	Contains Sufficient material for 40 tests		

ADVANCED QUALITY™

ITP02152-TC25
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ITP02153-TC10
ITP02153-TC40

ONE STEP Anti-HIV (1&2) Test

Diagnostic Kit for Antibody to Human Immunodeficiency Virus (Colloidal Gold) (Whole Blood/Serum/Plasma)

For in vitro diagnostic use only

Please read this package insert carefully prior to use and strictly follow the instructions. Reliability of the assay cannot be guaranteed if there are any deviations from the instructions in this package insert.

INTENDED USE

The ONE STEP Anti-HIV (1&2) Test is a colloidal gold enhanced, rapid immunochromatographic assay for qualitative detection of antibodies to Human Immunodeficiency Virus (HIV) in human whole blood, serum or plasma. This test is a rapid test used as an aid for diagnosis and all positive results must be confirmed using an appropriate test such as immunoblot assay or equivalent. This test is intended for healthcare professionals and trained healthcare workers use.

SUMMARY

Human immunodeficiency virus is the pathogen of Acquired Immunodeficiency Syndrome (AIDS)[1-2]. The ONE STEP Anti-HIV (1&2) Test is a simple, visual qualitative test that detects antibodies in human whole blood, serum or plasma. This test is simple, convenient and gives a result within 20 minutes.

TEST PRINCIPLE

The test region on the nitrocellulose membrane is pre-coated with recombinant HIV antigen (containing predominant epitope of gp41, gp120 of HIV-Ⅰ and predominant epitope of gp36 of HIV-Ⅱ), and the control region on the nitrocellulose membrane is pre-coated with sheep anti-rabbit IgG. The fiberglass is pre-coated with recombinant HIV antigen (containing predominant epitope of gp41, gp120 of HIV-Ⅰ and predominant epitope of gp36 of HIV-Ⅱ) conjugated with colloidal gold and rabbit IgG conjugated with colloidal gold. For positive specimens, HIV antigen conjugated with colloidal gold reacts with HIV antibody in whole blood, serum or plasma, forming a colloidal gold conjugate/HIV antibody complex. The complex migrates through the test strip and is captured by the recombinant HIV antigen immobilized in the test region, forming a colored test band. A negative specimen does not produce a test band due to the absence of colloidal gold conjugate/HIV antibody complex. To ensure assay validity, a colored control band in the control region appears at the end of the test procedure regardless of the test result.

STORAGE CONDITIONS AND STABILITY

The shelf life of ONE STEP Anti-HIV (1&2) Test is 24 months from date of manufacturing. Unused kit shall be stored at 2-30℃. If stored in refrigeration, the kit shall be taken out of the refrigerator and allowed sufficient time to recover to room temperature (10-30℃) prior to use. Sample diluent shall be used up within 8 weeks after first open.

⚠ WARNINGS AND PRECAUTIONS [3-4]

1. The test is intended for in vitro diagnostic use only.
2. This test is a rapid test used as an aid for diagnosis and all positive results must be confirmed using an appropriate test such as immunoblot assay or equivalent.
3. All specimens shall be treated as potentially infectious. Gloves and protective clothing must be worn when handling the specimen.
4. Operate according to standard safety precautions when disposing of biohazardous materials.
5. Used test cassette must be decontaminated before being discarded.
6. DO NOT use expired reagents or test cassettes.
7. DO NOT interchange reagents among kits with different lot No.
8. DO NOT use the Disposable Safety Lancets if the cap is already pulled off.
9. DO NOT reuse test cassettes and any disposable accessories (test cassette, plastic dropper, Sample diluents, Disposable Safety Lancets, Disposable Swabs, desiccant).
10. DO NOT use it if the foil pouch is damaged or broken.
11. DO NOT use the Disposable Swabs if the pouch is damaged.
12. Sample diluents contain sodium azide. Sodium Azide can react with copper and lead used in certain plumbing systems to form metal salts which are explosive. The quantities used in this kit are small, nevertheless when disposing of sodium azide containing materials, they should be flushed away with relatively large quantities of water to prevent metal azide building up in plumbing system.

REAGENT AND MATERIALS PROVIDED

Component	25 tests (product code ITP02152-TC25)	40 tests (product code ITP02152-TC40)	10 tests (product code ITP02153-TC10)	40 tests (product code ITP02153-TC40)
Test cassette	25	40	10	40
Dropper	25	40	10	40
Sample Diluents	3×2mL bottles	4×2mL bottles	10× 0.5mL bottles	4×2mL bottles

Component	25 tests (product code ITP02152-TC25)	40 tests (product code ITP02152-TC40)	10 tests (product code ITP02153-TC10)	40 tests (product code ITP02153-TC40)
Disposable Safety Lancets	Not provided	Not provided	10	40
Disposable Swabs	Not provided	Not provided	10	40
Package Insert	1	1	1	1

Note: information of disposable safety lancets and Disposable Swabs

Accessory	Manufacturer	Authorized Representative	CE mark (MDD)
Disposable Safety Lancets	SteriLance Medical (Suzhou) Inc. No.68 Litanghe Road, Xiangcheng, Suzhou, China	EMERGO EUROPE Molenstraat 15, 2513 BH, The Hague, The Netherlands	CE 0197
Disposable Swabs			CE

MATERIALS REQUIRED BUT NOT PROVIDED

- timer or stopwatch
- blood sampling tools (lancet, capillary, venous puncture device, etc.)
- biohazard waste container
- disposable gloves

SPECIMEN COLLECTION AND STORAGE[5]

Fingertip whole blood

1. 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. Prick the skin of the fingertip side with the Safety Lancets (for the provided Disposable Safety Lancets: twist off the protective cap and remove it. Place Lancet firmly on the finger and lancet will trigger), and keep the fingertip 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.
2. Collect the blood specimen with the dropper provided. Gently squeeze the bulb of the dropper and touch the tip to a drop of blood. Release the bulb to draw up the blood

Venous whole blood

1. With standard venous blood sampling process, collect whole blood specimen in a tube with any of the regular anticoagulants (EDTA, heparin sodium or sodium citrate). Other anticoagulants may lead to incorrect results. The whole blood specimen can be stored at 2-8℃ for 3 days, if it is not used immediately after being sampled. Before testing, mix the blood tube by shaking gently or shaker to ensure a homogeneous specimen.
2. Collect the blood specimen with the dropper provided.Gently squeeze the bulb of the dropper and touch the tip to a drop of blood. Release the bulb to draw up the blood.

Serum or plasma

1. Serum
   With standard venous blood sampling process, collect whole blood specimen in a tube without any of the regular anticoagulants (EDTA, heparin sodium or sodium citrate). Keep for 30 minutes for blood coagulation and obtain serum specimen of supernatant after centrifuging (at least 5 minutes at 3000rpm).
2. Plasma
   With standard venous blood sampling process, collect whole blood specimen in a tube with any of the regular anticoagulants (EDTA, heparin sodium or sodium citrate). Obtain plasma specimen after centrifuging (at least 5 minutes at 3000rpm).

Notes:

(1) Serum or plasma specimens shall be kept refrigerated at 2-8℃ .For specimens stored over 7 days, freezing at -20℃ or below is recommended (avoid multiple free-thaw cycles, 3 at most). Frozen specimens shall be thawed and allowed to recover to room temperature (10-30℃) before testing

(2) Serum or plasma specimen containing precipitate may lead to inconsistent results. Such specimens have to be cleared before use by centrifugation.

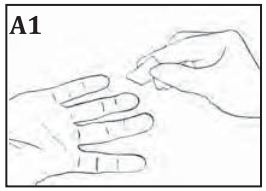
(3) This reagent is suitable for whole blood, serum or plasma specimens. It will not obtain an accurate result if used for other types of specimens such as saliva, urine etc.

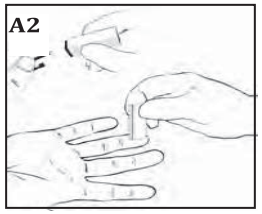
TEST PROCEDURE

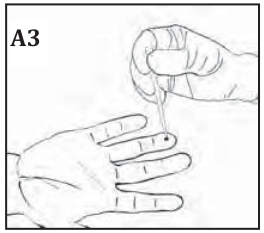
Do not open the pouch until ready to perform a test. It is suggested the single-use test be used under low environment humidity(RH≤70%) within 1 hour.

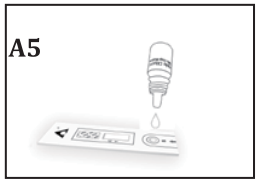
Test procedure for Fingertip whole blood

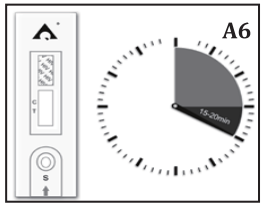
1. Leave all reagents and specimens to reach room temperature(10-30℃);
2. Take out test cassette from aluminum foil pouch and put it on a clean and dry surface;
3. Mark patient ID numbers on test cassette;
4. Rub the finger to stimulate blood flow, clean the subject's finger with the Disposable Swabs (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 of the fingertip side with the Safety Lancets (for the provided Disposable Safety Lancets: twist off the protective cap and remove it. Place Lancet firmly on the finger and lancet will trigger), and keep the fingertip 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 dropper provided. (Gently squeeze the bulb of the dropper and touch the tip to a drop of blood. Release the bulb to draw up the blood.) (Figure A3)
7. Add 30μl (or 1 drop by the provided dropper) of fingertip 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).





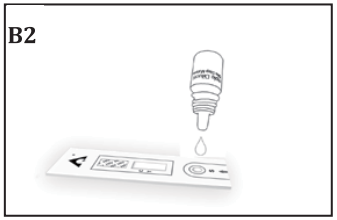


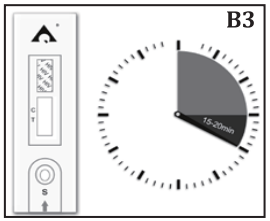




Test procedure for Venous whole blood

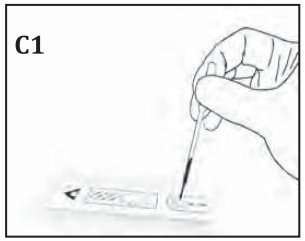
1. Leave all reagents and specimen to reach room temperature(10-30℃);
2. Take test cassette out of aluminum foil pouch and put it on a clean and dry surface;
3. Mark patient ID number on test cassette;
4. Add 30μl (or 1 drop by the provided dropper) of venous whole blood to the Sample Port (Port S) on test cassette; (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).

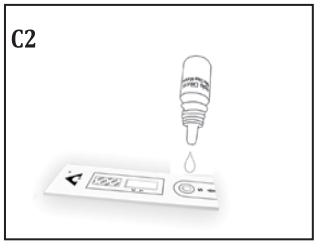


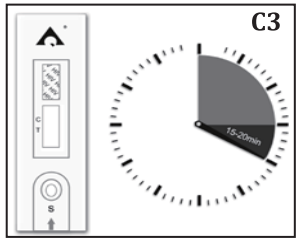


Test procedure for Serum or plasma

1. Leave all reagents and specimen to reach room temperature(10-30℃);
2. Take test cassette out of aluminum foil pouch and put it on a clean and dry surface;
3. Mark patient ID number on the cassette;
4. Add 30μl (or 1 drop by the provided dropper) of serum or plasma to the Sample Port (Port S) on test cassette; (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).







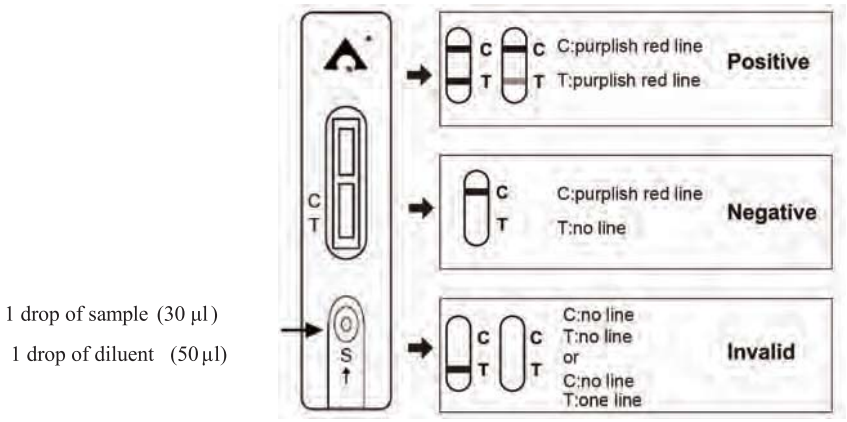
Caution: Always apply specimen with a new and clean dropper or pipette tip, to avoid cross contamination

It is recommended to run a known positive control and negative control at regular time intervals to ensure validity of the assay.

Note:

1. Normally the positive results detected in 15-20 minutes do not change any more. Nevertheless, DO NOT interpret the result after 20 minutes.
2. Positive specimens with a high concentration of HIV antibody may display results already before 15 minutes.
3. Negative results cannot rule out the possibility of exposure to or infection with HIV-1 or HIV-2 viruses.

TEST RESULT AND INTERPRETATION



1. **Positive**: Both purplish red test band and purplish red control band appear on the membrane.
2. **Negative**: purplish red control band only appears on control line. No band on test line indicates a negative result.
3. **Invalid**: The test is considered invalid if there is no purplish red control band. Use new Individual test to repeat the test.

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

Note: This test is a rapid test used as an aid for diagnosis and all positive results must be confirmed using an appropriate test such as immunoblot assay or equivalent.

PERFORMANCE CHARACTERISTICS

The performance of the ONE STEP Anti-HIV (1&2) Test has been evaluated by testing specimens from blood donors, from hospitalized patients and commercial seroconversion panels. The performance evaluations were conducted in two European sites to verify compliance with the requirements of the Common Technical Specifications 2002/364/EC, as amended by Commission Decision 2009/108/EC[6-7].

1. Sensitivity

A study was performed using specimens with confirmed HIV-positive status.

Table 1 Performance on HIV positive specimens

Specimen Types		Positive by Advanced Quality ™ ONE STEP Anti-HIV(1&2) Test	Total specimens tested	Sensitivity
HIV-1 positive specimens		260	260	100% 95%CI (98.59-100.00)
HIV-1 positive specimens belonging to different subtypes (non-B)		40	40	100% 95%CI (91.19-100.00)
Paired HIV-1 positive whole blood/plasma specimens	whole blood	100	100	100% 95%CI (96.38-100.00)
	plasma	100	100	100% 95%CI (96.38-100.00)
HIV-2 positive specimens		100	100	100% 95%CI (96.38-100.00)

2. Performance on commercial seroconversion panels

Table 2 Performance on commercial seroconversion panels

Panel ID	Reference ELISA A	Reference ELISA B	ONE STEP Anti-HIV（1&2）Test
	Number of reactive panel members/total number tested		
PRB914-N*	5/5	5/5	5/5
PRB916-P*	3/6	2/6	2/6
PRB919-S*	2/3	2/3	2/3
PRB924-X*	4/8	3/8	3/8

Panel ID	Reference ELISA A	Reference ELISA B	ONE STEP Anti-HIV（1&2）Test
	Number of reactive panel members/total number tested		
PRB925-Y*	2/6	2/6	2/6
PRB926-Z*	3/6	2/6	2/6
PRB930-AE	2/4	2/4	2/4
PRB934-AI*	3/3	2/3	2/3
PRB945-AU	3/6	2/6	3/6
PRB947-AW*	3/4	3/4	3/4
PRB950-AZ*	1/4	1/4	1/4
PRB951-BA*	3/6	1/6	1/6
PRB952-BB*	2/6	2/6	3/6
PRB953-BC*	1/4	1/4	1/4
PRB954-BD*	1/7	0/7	1/7
PRB955-BE*	3/5	2/5	2/5
PRB957-BG*	2/7	1/7	2/7
PRB959-BI*	6/7	4/7	5/7
PRB968	4/10	2/10	4/10
PRB969	3/10	3/10**	3/10
Total score	56/117	42/117	49/117

The ONE STEP Anti-HIV(1&2) Test detected HIV antibodies in 49 out of the 117 panel members, whereas the third generation reference ELISA tests, detected 42 panel members.

For all seroconversion panels the ONE STEP Anti-HIV(1&2) test was able to detect at least the same panel members as the third generation reference ELISA test, for 6 panels the ONE STEP Anti-HIV(1&2) Test detected one panel member more than the third generation reference ELISA assay.

3. Specificity

Table 3 Performance on HIV negative specimens

Specimens Types	ONE STEP Anti-HIV (1&2) Test			
	Negative	positive	Total	Specificity
Whole blood specimens	500	0	500	100% 95%CI（99.26-100.00）
EDTA plasma specimens negative for HIV	1000	0	1000	100% 95%CI（99.63-100.00）
Hospitalized patient specimens	200	0	200	100% 95%CI（98.17-100.00）
Specimens from pregnant women	200	0	200	100% 95%CI（98.17-100.00）

4. Performance on cross-reactivity

Table 4 Performance on cross-reactivity

Interferent specimens	ONE STEP Anti-HIV (1&2) Test		
	Negative	positive	Total
Rheumatoid factor positive	10	0	10
anti-HCV positive	18	0	18
anti-HBs positive	18	0	18
anti-HBc positive	18	0	18
Anti-HTLV 1/2 positive	18	0	18
anti-HEV positive	18	0	18
Total	100	0	100

5. Performance on fresh specimens

In total 25 fresh specimens were with the Advanced Quality ™ ONE STEP Anti-HIV 1&2 assay and spiked with anti-HIV and tested.

Table 5 Reproducibility of test results

	Day 0	Day 1	Day 2	Day 3	Day 4
Negative specimens	25/25				
Spiked specimens	25/25	25/25	25/25	25/25	25/25

Reproducibility of spiked specimens was 100.0% over the study period of 5 days.

6. Performance on specimen types

Whole blood:

Sensitivity obtained on 100 paired whole blood/plasma of positive patients was 100% for both specimen types (refer to Table 1).

Specificity obtained on 500 whole blood specimens of blood donors was 100% (refer to Table 3).

Serum/plasma

Table 6 Serum/Plasma comparison test with HIV-negative specimens

	EDTA plasma	Heparin plasma	Citrate plasma	serum
Tested	25	25	25	25
Test negative	25	25	25	25
Test positive	0	0	0	0
Specificity	100%	100%	100%	100%

Table 7 Serum/Plasma comparison test with HIV-positive specimens

	EDTA plasma	Heparin plasma	Citrate plasma	serum
Tested	25	25	25	25
Test negative	0	0	0	0
Test positive	25	25	25	25
Sensitivity	100%	100%	100%	100%

The test results showed concordance between plasma (EDTA, Heparin and Citrate) and serum specimens.

Table 8 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.

LIMITATION

1. Only specimens with good fluidity and without hemolysis can be used with this test;
2. Use of fresh specimen is recommended. Refrigerated specimens and frozen specimens can also be used after being allowed to recover to room temperature (10-30℃) and full homogeneity. Do not freeze and thaw whole blood specimen.
3. This test is a rapid test used as an aid for diagnosis and all positive results must be confirmed using an appropriate test such as immunoblot assay or equivalent.
4. This test may generate false negative results in case of very low antibody concentrations.

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