WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: ONE STEP Anti - HIV (1&2) Test
WHO reference number: PQDx 0372-017-00

ONE STEP Anti - HIV (1&2) Test with product codes **ITPW02152-TC40, ITPW02152-TC25, ITPW02153-TC40, ITPW02153-TC40SA and ITPW02154-TC40** manufactured by **InTec PRODUCTS, INC, Rest-of-World regulatory version** was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 17 May 2019.

Summary of WHO prequalification assessment for ONE STEP Anti - HIV (1&2) Test.

	Date	Outcome
Prequalification listing	17 May 2019	Listed
Dossier review	N/A	N/A
Site inspection(s) of quality management system	27- 30 September 2018	MR
Product performance evaluation	Quarter of 2018	MR

MR: Meet Requirements
N/A: Not Applicable

Report amendments and product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Summary of amendment	Date of report amendment
2.0	Addition of a new product code (ITPW02153-TC40SA) for the South African tender RT41-2020, resulting in modification on the Prequalified HIV product labelling and dropper provided.	12 February 2020
3.0	Addition of one product code, ITPW02154-TC40, which is almost identical to the existing configuration ITPW02153-TC40 except the new code is provided with a new safety	30 October 2023

	lancet of a different brand (new lancet is also CE marked as the used lancet in existing code ITPW02153-TC40.	

Intended use:

According to the claim of InTec PRODUCTS, INC, *"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 (venous and fingerstick), serum or plasma. This test is intended for healthcare professionals and trained healthcare workers to use as an aid in HIV infection diagnosis of adult healthcare patients".*

Assay Description:

According to the claim of InTec PRODUCTS, INC, "The *test band region on the nitrocellulose membrane is pre-coated with recombinant HIV antigen (containing predominant epitope of gp41, gp120 of HIV-1 and predominant epitope of gp36 of HIV-2), and the control band 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-1 and predominant epitope of gp36 of HIV-2) 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 band region, forming a test band.
A negative specimen will not produce a test band due to the absence of colloidal gold conjugate/HIV antibody complex. To ensure assay validity, a purplish red control band in the control region will appear regardless of the test result. The assay is only valid when the control band appears".

Test kit contents:

Component	**25 Tests/kit (T/k) (product code ITPW02152-TC25)**	**40 T/k (product code (ITPW02152-TC40)**	**40 T/k (product code (ITPW02153-TC40/ ITPW02153-TC40SA)**	**40 T/k (product code ITPW02154-TC40)**
Test cassette	1×25 pieces	1×40 pieces	1×40 pieces	1×40 pieces
Dropper	1×25 pieces	1×40 pieces	1×40 pieces	1×40 pieces
Sample diluent	2mL×3 bottles	2mL×4 bottles	2mL×4 bottles	2mL×4 bottles
Sterile Safety lancet	Not provided	Not provided	1×40 pieces (05-062122)	1×40 pieces (21G)
Alcohol swab	Not provided	Not provided	1×40 pieces	1×40 pieces
Package insert	1×1 piece	1×1 piece	1×1 piece	1×1 piece

Items required but not provided:

- Timer or stopwatch
- Blood sampling tools (sterile gauze pad, venous puncture device, collection tube with EDTA/heparin sodium/sodium citrate for whole blood or plasma, collection tube with no anticoagulant for serum.)
- Biohazard waste container
- Disposable gloves

Storage:
The test kit should be stored at 2-30°C.

Shelf-life upon manufacture:
24months.

Warnings/limitations:

Refer to the latest version of the manufacturer's instructions for use.

Prioritization for prequalification
Based on the established eligibility criteria, the **ONE STEP Anti - HIV (1&2) Test** was given priority for the WHO prequalification assessment.

Product dossier assessment

In accordance with the WHO procedure for abridged prequalification assessment, **InTec PRODUCTS** was not required to submit a product dossier for the **ONE STEP Anti - HIV (1&2) Test** as per the *"Instructions for compilation of a product dossier"* (PQDx_018 version 3). Notwithstanding, certain aspects of the product dossier previously submitted for stringent regulatory review were reviewed by an assessor during the site inspection.

Manufacturing site inspection

In accordance with the WHO procedure for abridged prequalification assessment, a shortened inspection with fewer inspectors was conducted at the site(s) of manufacture (at 308, Wengjiao Rd, Xinyang IND.AREA, Haicang, Xiamen, 361022, China) of ONE STEP Anti - HIV (1&2)in August 2018 as per the "*Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics*" (PQDx_014 version 4).

The inspection found that the manufacturer had an acceptable quality management system and good manufacturing practices in place that ensured the consistent manufacture of a product of good quality.

The manufacturer's responses to the nonconformities found at the time of the inspection were accepted on 5 March 2019.

Based on the site inspection and corrective action plan review, the quality management system for ONE STEP Anti‑HIV (1&2) meets WHO prequalification requirements.

Product performance evaluation

ONE STEP Anti-HIV (1&2) Test is a rapid diagnostic test (RDT) assay for the qualitative detection of HIV-1/2 antibodies in human whole blood, serum or plasma. A volume of 30 µL of specimen is needed to perform the assay. This type of assay requires no sophisticated equipment and can, therefore, be performed in laboratories with limited facilities and non-laboratory settings. Reading of the results can be done visually, i.e. subjectively read.

ONE STEP Anti-HIV (1&2) Test was evaluated by WHO in the 4th quarter of 2018 at the National Health Laboratory Quality Assurance and Training Centre, Dar el Salaam, Tanzania, using serum specimens. From this evaluation, we drew the following conclusions:

In this limited evaluation on a panel of 1196 clinically-derived serum specimens, compared to the reference diagnostic algorithm (Murex HIV Ag/Ab Combination, DiaSorin S.p.A, UK, and Genscreen ULTRA HIV Ag-Ab, Biorad Laboratories; followed by INNO-LIA HIV I/II Score (Fujirebio)), the following performance characteristics were obtained:

Performance characteristics in comparison with an agreed reference standard		
	Initial (95% CI)	**Final (95% CI)**
Sensitivity % (N=470)	100% (99.2% - 100%)	100% (99.2% - 100%)
Specificity % (N=726)	100% (99.5% - 100%)	100% (99.5% - 100%)
Invalid rate %	0	
Inter-reader variability %	0	

In addition, analytical performance characteristics were assessed using commercially available and locally-made panels and the following results were obtained:

Additional performance characteristics	
Sensitivity during seroconversion on 7 seroconversion panels in comparison with a benchmark assay (Murex HIV Ag/Ab, DiaSorin, S.p.A)	Seroconversion sensitivity index of +0.7. Therefore, detection is 0.7 specimens later than the benchmark assay.
Analytical sensitivity on a mixed titer panel in comparison with an agreed reference standard	17 of 17 specimens were correctly classified.
HIV subtype detection using the WHO reference panel for anti-HIV	All specimens were correctly classified
Lot to lot variation on a dilution panel	Acceptable

Key operational characteristics	
Validated specimen types (according to the IFU)	Serum, plasma (EDTA, heparin sodium or sodium citrate), venous whole blood, capillary whole blood
Number of steps	2 without precision pipetting required
Time to result	15 minutes
Endpoint stability	5 minutes (the test should be read between 15 and 20 minutes after addition of sample diluent)
Internal QC	Yes, the control line on the test device (reagent control).
In-use stability of reagents	Sample diluent shall be used within 8 weeks after the first opening.

Limitations of the performance evaluation:

1. All specimens used in the performance evaluation were from the same geographical area.

2. All positive specimens in the performance evaluation were positive for HIV-1, so the sensitivity of the ONE STEP Anti-HIV (1&2) Test for the detection of HIV-2 could not be assessed.

Labelling

1. **Labels**
2. **Instructions for use**

1.0 Labels

1.1 Product code ITPW02152-TC40 Labels

01.05.11.073-190702

ITPW02152-TC40

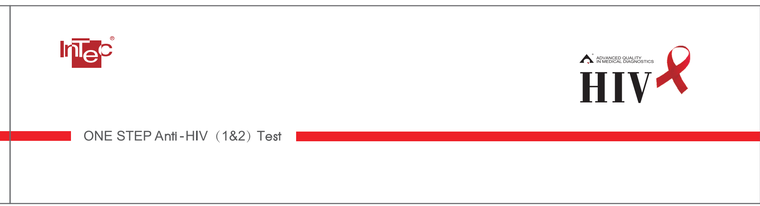
C 0 M 0 Y 0 K 100

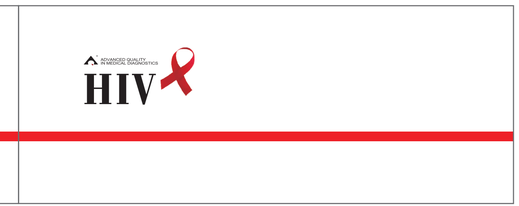
C 30 M 100 Y 100 K 0

C 0 M 100 Y 95 K 100

C 0 M 0 Y 0 K 80

235*155*62mm





01.05.11.073-190702

以下备注无需印刷出来

测试卡纸盒盒贴（侧面）
Test Card Label (Left Side)

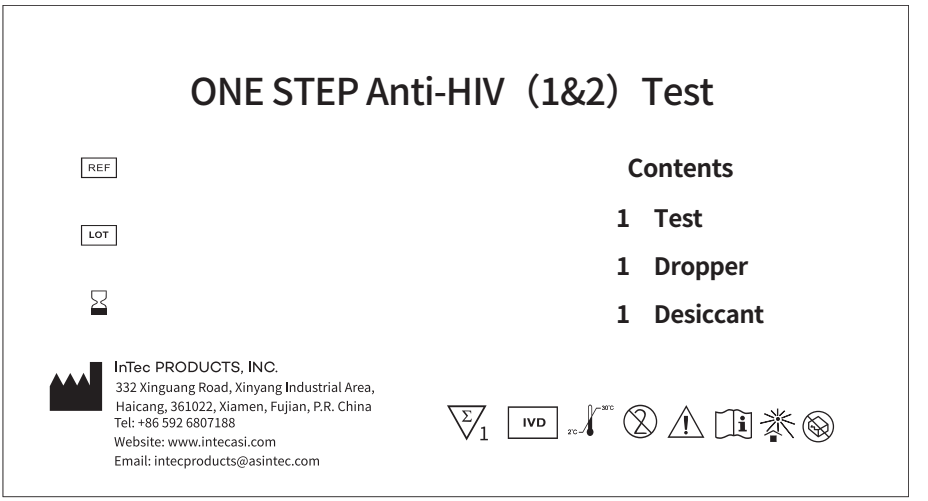
Size: 55*30mm Colour: C 0 M 0 Y 0 K 80

Font: Arial Type Size : 8 Line Spacing : 12

Distributor Information
40*22mm
Type Size :8
Line Spacing :12

Foil Bag (card)

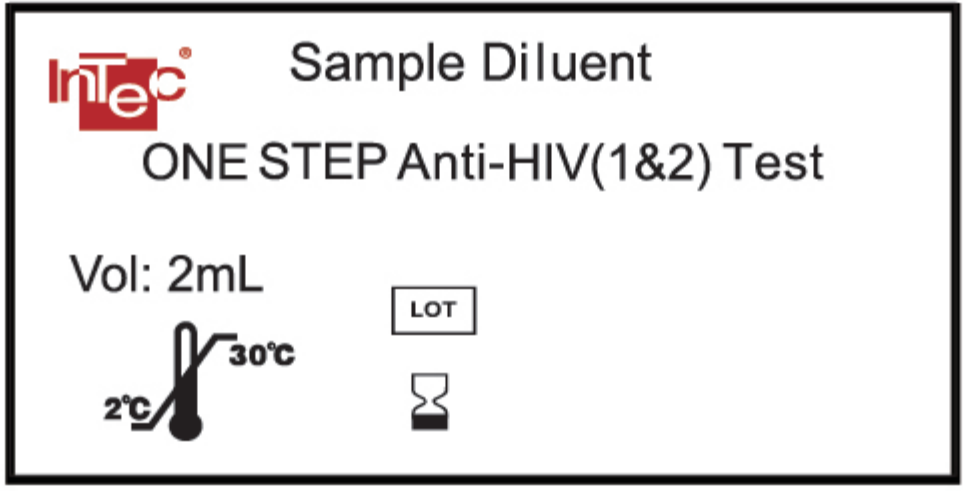
01.05.13.033-220502



120*65MM

Sample Diluent label 40*20mm

01.05.12.029-190601



1.2 Product code and ITPW02152-TC25

01.05.11.072-190702

ITPW02152-TC25

C 0 M 0 Y 0 K 100

C 30 M 100 Y 100 K 0

C 0 M 100 Y 95 K 100

C 0 M 0 Y 0 K 80

190*120*65mm

01.05.11.072-190702

以下备注无需印刷出来

测试卡纸盒盒贴（侧面）
Test Card Label (Left Side)

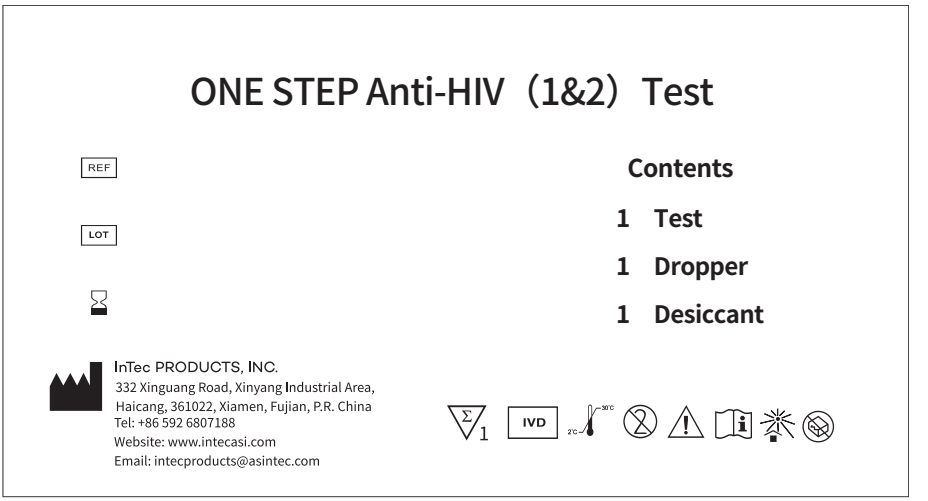
Size: 55*30mm Colour: C 0 M 0 Y 0 K 80

Font: Arial Type Size : 8 Line Spacing : 12

Distributor Information
40*22mm
Type Size :8
Line Spacing :12

Foil Bag (card)

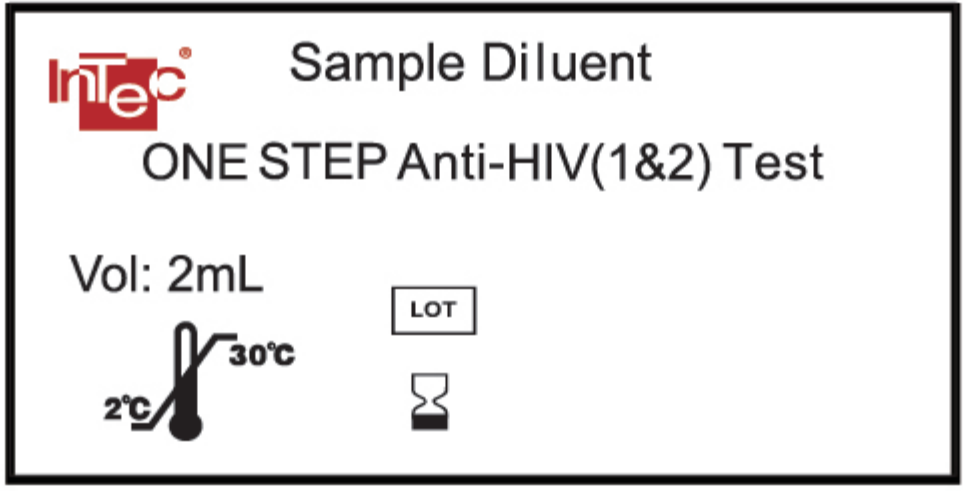
01.05.13.033-220502



120*65MM

Sample Diluent label 40*20mm

01.05.12.029-190601



1.3 Product code ITPW02153-TC40

01.05.11.074-221104
ITPW02153-TC40　ITPW02154-TC40

Spec.220*135*85mm　350g paper board

PT187C

C 0　M 100　Y 95　K 0

C 0　M 0　Y 0　K 100

InTec PRODUCTS, INC.

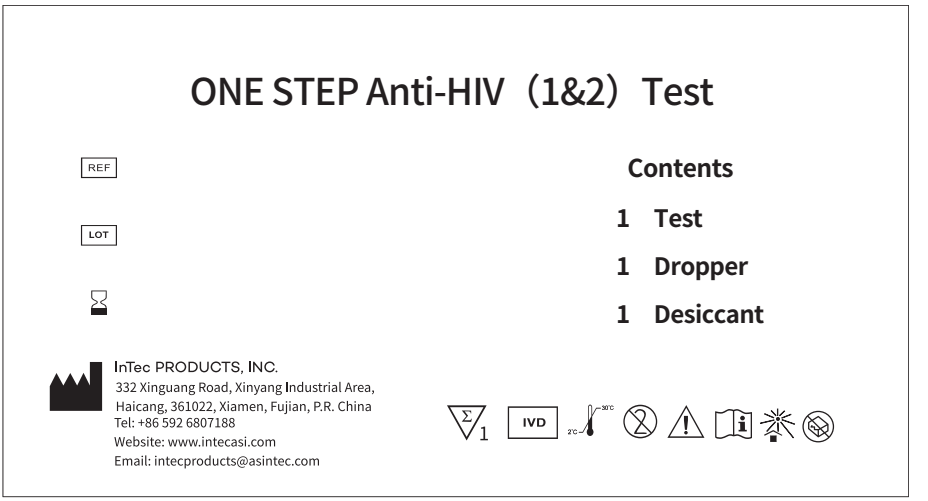
InTec PRODUCTS, INC.
332 Xinguang Road, Xinyang Industrial Area,
Haicang, 361022, Xiamen, Fujian, P.R. China

Tel: +86 592 6807188
Website: www.intecasi.com
Email: intecproducts@asintec.com

ONE STEP Anti-HIV（1&2）Test

Foil Bag (card)

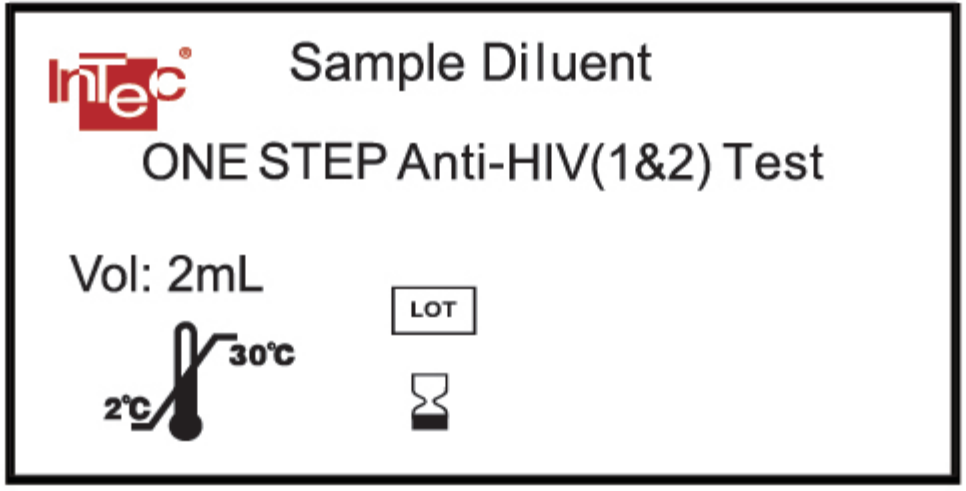
01.05.13.033-220502



120*65MM

Sample Diluent label 40*20mm

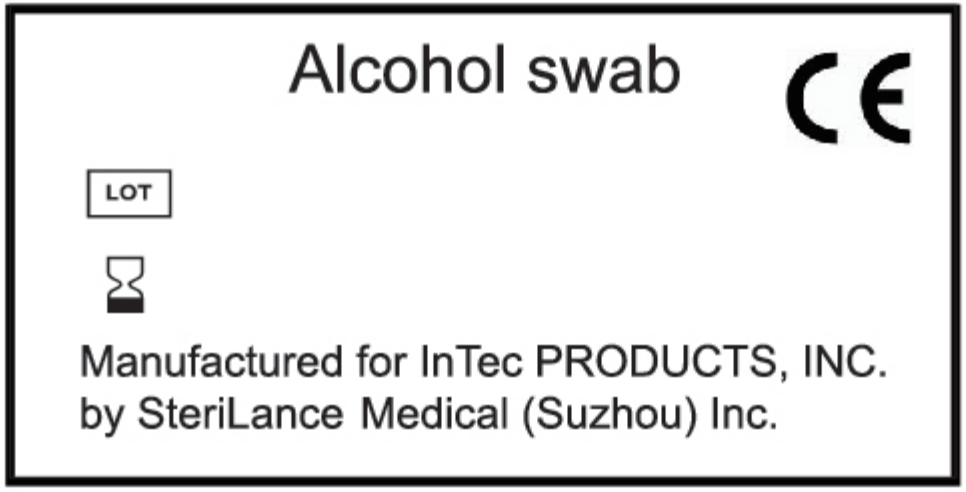
01.05.12.029-190601



4 Alcohol swabs label (secondary)

40*20mm

01.04.01.193-190601



4 Alcohol swab label
Front view

STERILANCE®

Skin Prep Pads

ISOPROPYL ALCOHOL, 70% BY VOLUME

FOR EXTERNAL ANTISEPTIC
USE ONLY

CONTAINS ONE PAD

DO NOT REUSE

4 Alcohol swab label
Back view

CE

Drug Facts

Active ingredient **Purpose**

Isopropyl Alcohol, 70% by volume.....Antiseptic

Uses: For antiseptic cleaning of the skin.

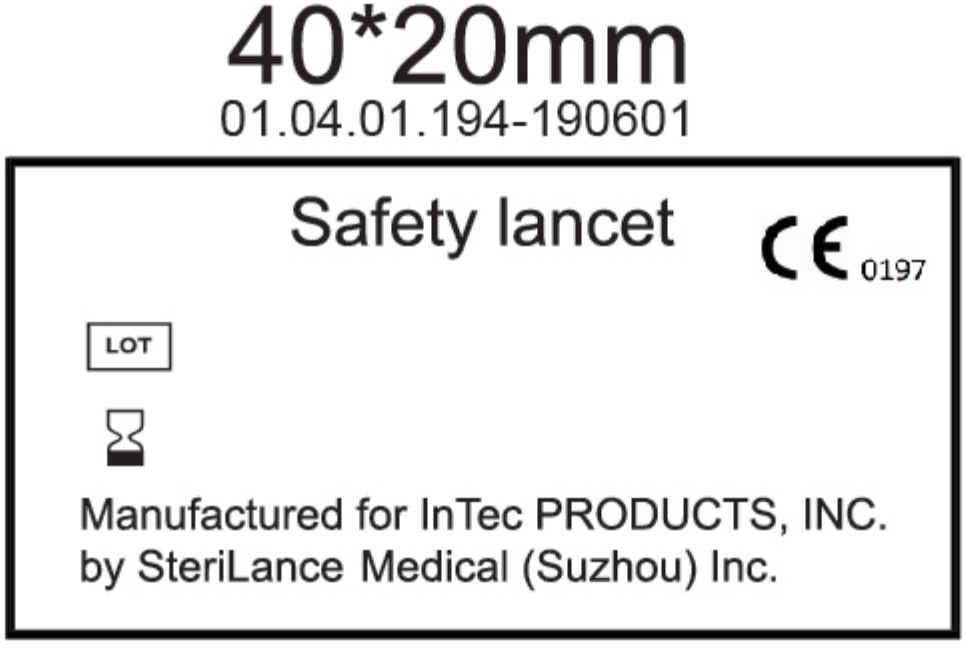
Warnings: For external use only. Flammable, keep away from fire or flame.

Do not use with electrocautery procedures, or in/near eyes. Stop use if irritation or redness develops.
If irritating condition persists for more than 72 hours, consult a physician. Keep out of reach of children. If swallowed, seek medical attention and/or contact a Poison Control Center immediately.

Directions: Prepare site by wiping vigorously.

Inactive ingredient: Purified water.

5 label of safey lancet



1.4 Product code ITPW02153-TC40SA labels

01.05.02.495-220802

Spec. 235*155*62mm 350g white board

ITPW02153-TC40SA

ADVANCED QUALITY IN MEDICAL DIAGNOSTICS

HIV

Colloidal Gold (Whole Blood/Serum/Plasma)

ONE STEP Anti-HIV (1&2) Test

Contents

40	Tests
40	Droppers
40	Desiccants
4	Sample Diluents
40	Alcohol Swabs
40	Safety Lancets
1	Pack Insert

REF ITPW02153-TC40SA

LOT

STERILE

IVD

Distributed by:
Armada Diagnostics
Tel: (011) 706 5525 / (011) 706 5500
Fax: 086 536 3359
E-mail: armadadiagnostics@mweb.co.za

InTec PRODUCTS, INC.

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

Tel: +86 592 6807100
Website: www.intecasi.com
Email: intecproducts@asintec.com

ONE STEP Anti-HIV（1&2）Test

01.05.02.495-220802Sp

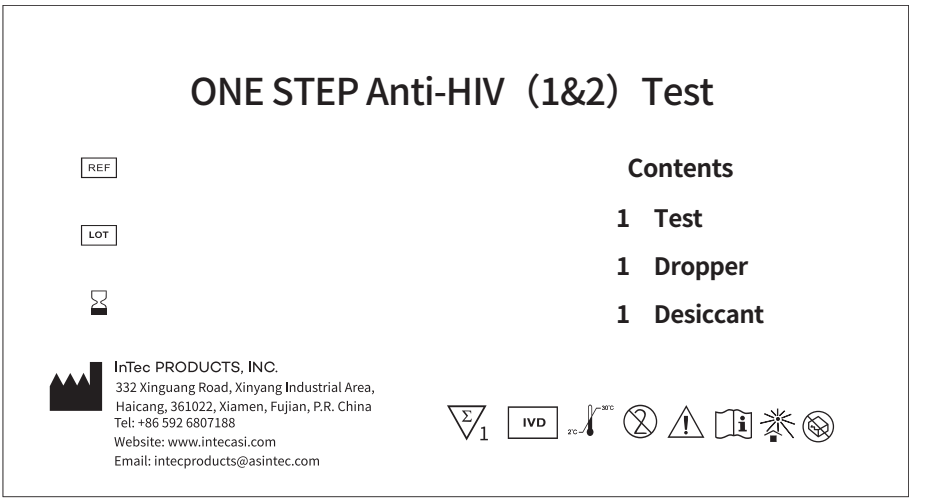
Test procedure

01. Do not open the pouch until ready to perform the test. Use the test immediately after opening the pouch;
02. Equilibrate all reagents and specimens to room temperature (10-30°C) before use;
03. Put on gloves;
04. Unseal the foil pouch and place the cassette on a clean, dry and level surface;
05. Write a client identifier on the test;
06. Clean the finger with an alcohol swab and leave it to dry;
07. Twist the lancet cap clockwise more than 180° and remove it;
08. Place the lancet firmly on the side of the finger (avoid callus) to trigger it;
09. Gently massage around the bleeding point. Wipe away the first drop of blood;
10. Gently squeeze the bulb of the dropper and touch the tip to a drop of blood. Release the bulb to collect blood past the tip of the dropper;
11. Add **1 drop** of the specimen (whole blood, serum or plasma) by gently squeezing the bulb of the dropper (or 30µl by transfer pipette) into the "**S**" well of the cassette;
12. Immediately add **1 drop** (50µl) of sample diluent into the "**S**" well;
13. Wait and interpret the result at 15 minutes, but not after 20 minutes.

Result interpretation

Foil Bag (card)

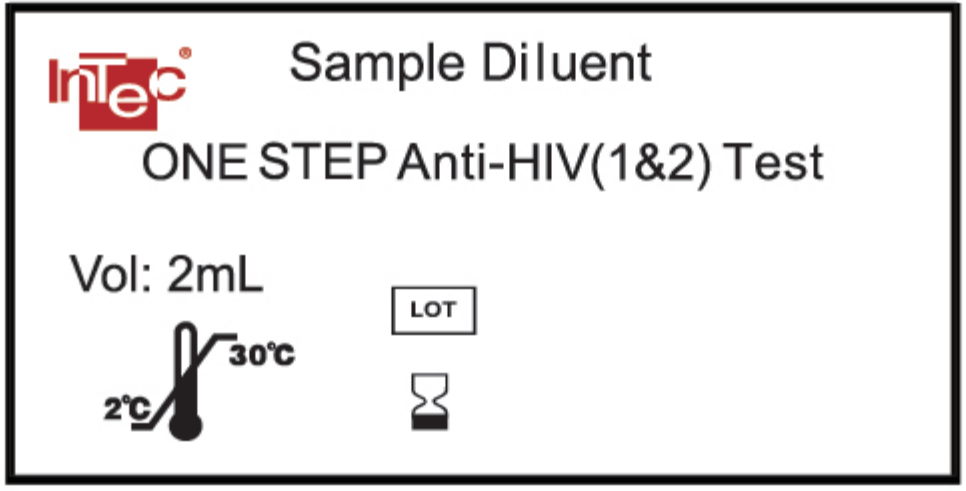
01.05.13.033-220502



120*65MM

Sample Diluent label 40*20mm

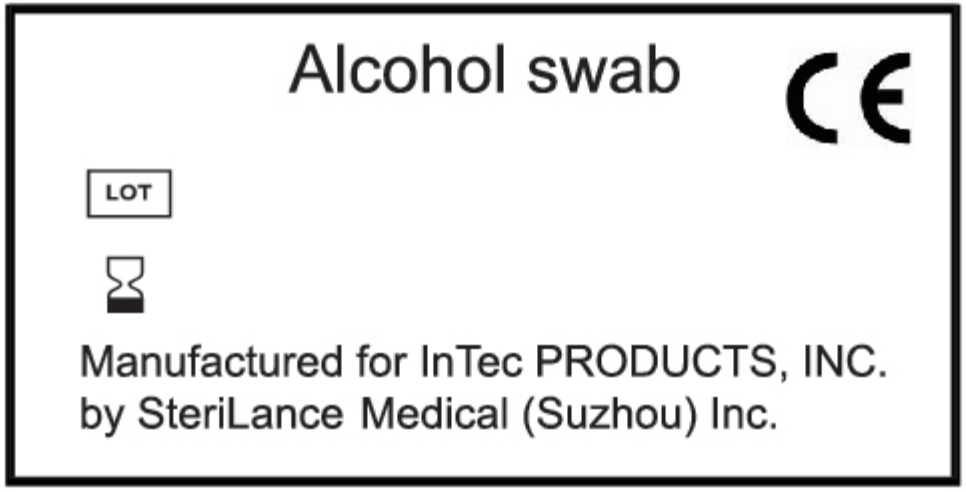
01.05.12.029-190601



4 Alcohol swabs label (secondary)

40*20mm

01.04.01.193-190601



4 Alcohol swab label
Front view

STERILANCE®

Skin Prep Pads

ISOPROPYL ALCOHOL, 70% BY VOLUME

FOR EXTERNAL ANTISEPTIC
USE ONLY

CONTAINS ONE PAD

DO NOT REUSE

4 Alcohol swab label
Back view

CE

Drug Facts

Active ingredient **Purpose**

Isopropyl Alcohol, 70% by volume.....Antiseptic

Uses: For antiseptic cleaning of the skin.

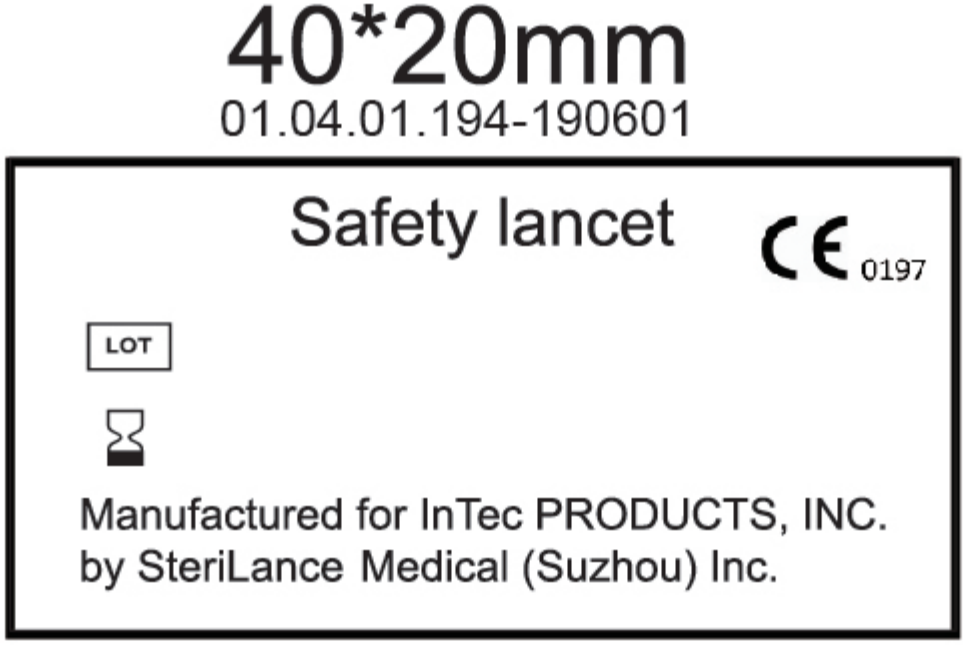
Warnings: For external use only. Flammable, keep away from fire or flame.

Do not use with electrocautery procedures, or in/near eyes. Stop use if irritation or redness develops.
If irritating condition persists for more than 72 hours, consult a physician. Keep out of reach of children. If swallowed, seek medical attention and/or contact a Poison Control Center immediately.

Directions: Prepare site by wiping vigorously.

Inactive ingredient: Purified water.

5 label of safey lancet



1.5 Product code ITPW02154-TC40 labels

01.05.11.074-221104

ITPW02153-TC40 ITPW02154-TC40

Spec.220*135*

01.05.11.074-221104

PT187C

ITPW02153-TC40, ITPW02154-TC40

C 0 M 100 Y 95 K 0

C 0 M 0 Y 0 K 100

ADVANCED QUALITY IN MEDICAL DIAGNOSTICS HIV

ADVANCED QUALITY IN MEDICAL DIAGNOSTICS HIV

InTec

ADVANCED QUALITY IN MEDICAL DIAGNOSTICS HIV

ADVANCED QUALITY IN MEDICAL DIAGNOSTICS HIV

ONE STEP Anti-HIV（1&2）Test

InTec PRODUCTS, INC.

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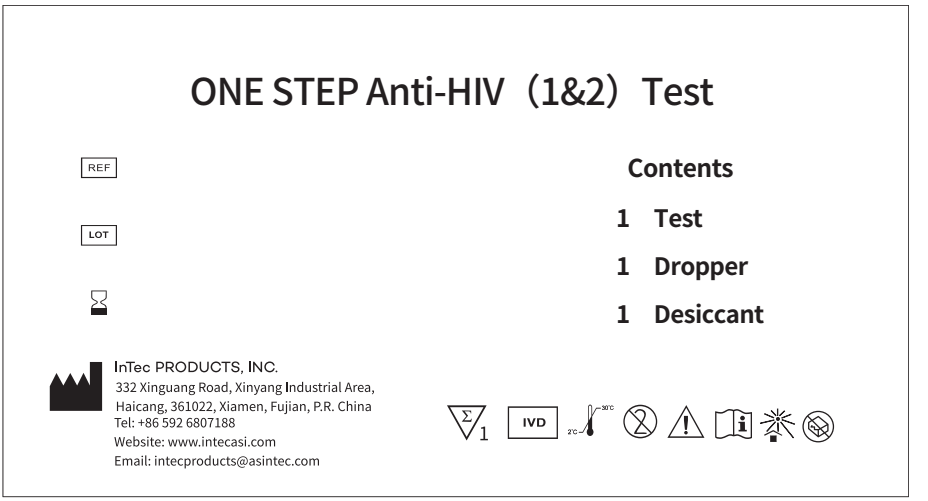
Haicang, 361022, Xiamen, Fujian, P.R. China

Tel: +86 592 6807188
Website: www.intecasi.com
Email: intecproducts@asintec.com

Foil Bag (card)

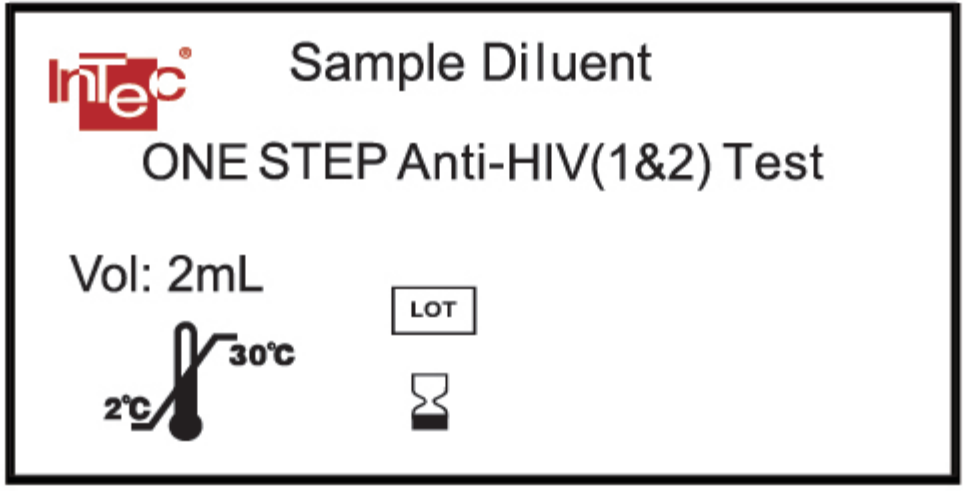
01.05.13.033-220502



120*65MM

Sample Diluent label 40*20mm

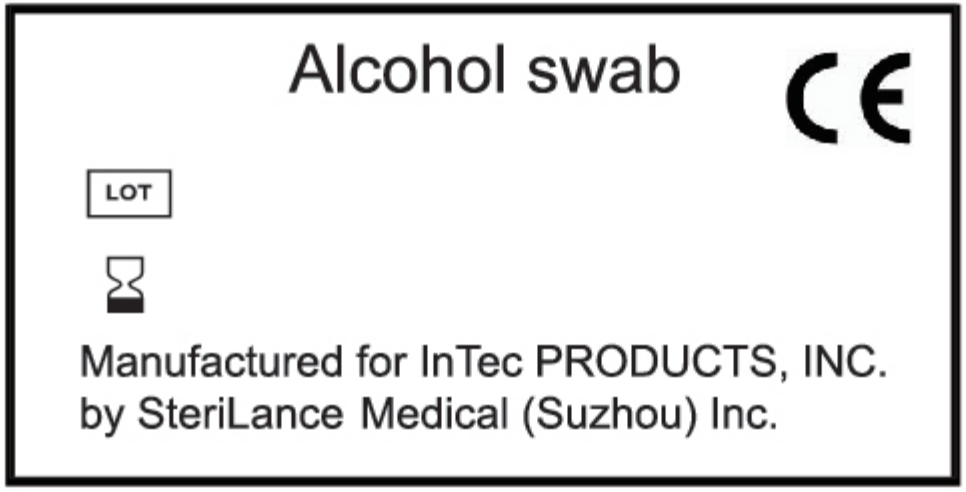
01.05.12.029-190601



4 Alcohol swabs label (secondary)

40*20mm

01.04.01.193-190601



4 Alcohol swab label
Front view

STERILANCE®

Skin Prep Pads

ISOPROPYL ALCOHOL, 70% BY VOLUME

FOR EXTERNAL ANTISEPTIC
USE ONLY

CONTAINS ONE PAD

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4 Alcohol swab label
Back view

CE

Drug Facts

Active ingredient — **Purpose**

Isopropyl Alcohol, 70% by volume.....Antiseptic

Uses: For antiseptic cleaning of the skin.

Warnings: For external use only. Flammable, keep away from fire or flame.

Do not use with electrocautery procedures, or in/near eyes. Stop use if irritation or redness develops.
If irritating condition persists for more than 72 hours, consult a physician. Keep out of reach of children. If swallowed, seek medical attention and/or contact a Poison Control Center immediately.

Directions: Prepare site by wiping vigorously.

Inactive ingredient: Purified water.

2.0 Instructions for Use[1]

[1] English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

Label of safey lancet

01.04.01.268-221001

	**Suzhou Kyuan Medical Apparatus Co., Ltd P.R.China**
EC REP	**Llins Service & Consulting GmbH** Add.: Obere Seegasse 34/2, 69124, Heidelberg, Germany Tel. 049/175 4870819 Fax. 175 4870819 E-mail: Llins Service@gmail.com
SPEC.: 21G	**Disposable Safety Lancets**

Direction for use

1. Preparation: Wash hands with soap and warm water thoroughly before and after using the device. Clean and disinfect the puncture part with alcohol and dry thoroughly by sterilized cotton.
2 Twist off the lancet protection cap;
3 Place the end face of the lancet on the selected site;
4 Press the shot to launch;
5 Processing the Lancet in a sharpscontainer.

LOT	**888-2020**					
	**2020-11**					
	**2025-10**	STERILE R		CE 0197		

Made in China

2.0 Instructions for use
2.1 Universal version IFU

ADVANCED QUALITY

REF ITPW02152-TC25
ITPW02152-TC40
ITPW02153-TC40
ITPW02154-TC40

01.05.14.076-230706
date：2023.07.03

ONE STEP Anti-HIV (1&2) Test

For *in vitro* diagnostic use only. IVD

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 (venous and fingerstick), serum or plasma specimens in adults. This test is intended for use by healthcare professionals and trained healthcare workers as an aid in the diagnosis of HIV infection.

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 and presents the result at 15 minutes, but not after 20 minutes.

Test Principle

The test band region on the nitrocellulose membrane is pre-coated with recombinant HIV antigen (containing predominant epitope of gp41, gp120 of HIV-1 and predominant epitope of gp36 of HIV-2), and the control band 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-1 and predominant epitope of gp36 of HIV-2) 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 band region, forming a test band.
A negative specimen will not produce a test band due to the absence of colloidal gold conjugate/HIV antibody complex. To ensure assay validity, a purplish red control band in the control region will appear regardless of the test result.
The assay is only valid when the control band appears.

Storage conditions and stability

The shelf life of *the ONE STEP Anti-HIV (1&2) Test*, including the sample diluent, is 24 months from date of manufacture. Product shall be stored at 2-30°C. Test cassette should be used immediately upon opening the foil pouch. Sample diluent should be stored capped at 2-30°C and used within 8 weeks after opening.

⚠ Warnings and precautions[3-4]

The warnings and precautions are included, but not limited to the following:

[Warnings]

- This product is for in vitro diagnosis of the infection of HIV only, other diseases cannot be analyzed with any component of this kit.
- All specimens with positive results must be confirmed using an appropriate test such as immunoblot assay or equivalent.
- 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 quantity used in this kit is small, however, when disposing sodium azide containing materials, flush with relatively large quantities of water to prevent metal azide build up in plumbing systems.

[Precautions]

- Wear gloves during the entire testing process.
- Do not use expired reagents or test cassettes.
- Do not use accessories if the seal or package is broken.
- Do not use test cassette if the foil pouch is damaged or the seal is broken.
- Do not use the provided sterile safety lancets if the cap is already pulled off before use.
- Do not reuse the accessories. All the accessories are for single use.
- Do not reuse the cassette. Each cassette enclosed in a foil pouch is only for single use.
- Do not pipette by mouth.
- Do not eat or smoke while handling specimens.
- Do not store the specimen in dropper , it is only used for specimen collection.
- Do not use pooled specimens or specimens other than specified (i.e. saliva,urine).
- Do not interchange reagents among kits of different batch number or even products.
- Do not perform the test in an environment which leads to rapid evaporation(e.g. ＞40°C and ＜40% relative humidity, close to a running fan or air conditioner).
- Ensure the specimen is added correctly prior to the addition of sample diluent.
- Avoid contact between the "S" well of the cassette and diluent bottle to prevent contamination of the diluent.
- Clean and disinfect all the areas that may be contaminated by spills of specimens or reagents with appropriate disinfectant.
- Decontaminate and dispose of all specimens, reagents, accessories and other potentially contaminated materials as infectious wastes in a biohazard container. Used lancet should be disposed of in a sharps bin.

Reagent and materials provided

Table 1 Reagent and materials provided

Component	25 tests ITPW02152-TC25	40 tests ITPW02152-TC40	40 tests ITPW02153-TC40	40 tests ITPW02154-TC40
Test cassette	1×25 pieces	1×40 pieces	1×40 pieces	1×40 pieces
Dropper	1×25 pieces	1×40 pieces	1×40 pieces	1×40 pieces
Desiccant	1×25 pieces	1×40 pieces	1×40 pieces	1×40 pieces
Sample diluent	2mL×3 bottles	2mL×4 bottles	2mL×4 bottles	2mL×4 bottles
Sterile safety lancet	Not provided	Not provided	1×40 pieces (05-062122)	1×40 pieces (21G)
Alcohol swab	Not provided	Not provided	1×40 pieces	1×40 pieces
Package insert	1×1 piece	1×1 piece	1×1 piece	1×1 piece

Preparation

1a. Open the foil pouch and look for the following components as below, if the product code is ITPW02153-TC40 or ITPW02154-TC40:

1b. Open the foil pouch and look for the following components as below, if the product code is ITPW02152-TC40 or ITPW02152-TC40:

2. Put on gloves.

3. Write a client identifier on the test.

I. Fingerstick whole blood

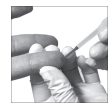
4. Clean the finger with an alcohol swab and leave it to dry.

5. Twist the lancet cap clockwise, more than 180° and remove it.

6. Place the lancet firmly on the side of the finger (avoid callus) Push lancet to trigger it.

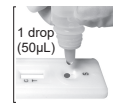
7. Gently massage around the bleeding point.Wipe away the first drop of blood.

8. Gently squeeze the bulb of the dropper and touch the tip to a drop of blood. Release the bulb to collect blood past the tip of the dropper.

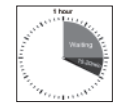


9. Add **1 drop** (30μL) of whole blood by gently squeezing the bulb of the provided dropper into the "**S**" Well.

10. Immediately add **1 drop** (50μL) of sample diluent into the "**S**" Well.



11. Wait and interpret the result at 15 min, but not after 20 min.



II. Venous whole blood

4a. Add **1 drop** (30μL) of whole blood by gently squeezing the bulb of the provided dropper into the "**S**" Well.

4b. Add **30μL** (1 drop) of whole blood using the transfer pipette into the "**S**" Well.

5. Immediately add **1 drop** (50μL) of sample diluent into the "**S**" Well .

6. Wait and interpret the result at 15 min, but not after 20 min.

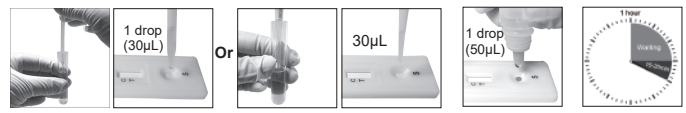
III. Serum/plasma

4a. Add **1 drop** (30μL) of specimen by gently squeezing the bulb of the provided dropper into the "**S**" Well.

4b. Add **30μL** (1 drop) of specimen using the transfer pipette into the "**S**" Well.

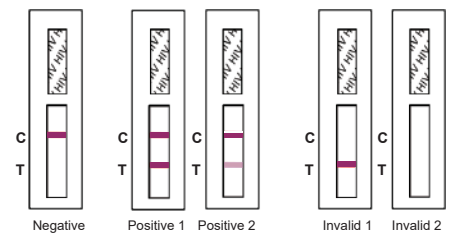
5. Immediately add **1 drop** (50μL) of sample diluent into the "**S**" Well .

6. Wait and interpret the result at 15 min, but not after 20 min.



Result interpretation

See package insert for details



Materials required but not provided

- Timer or stopwatch
- Blood sampling tools (sterile gauze pad, venous puncture device, collection tube with EDTA/heparin sodium/sodium citrate for whole blood or plasma, collection tube with no anticoagulant for serum.)
- Biohazard waste container and sharps bin
- Sterile safety lancet and alcohol swab (product code ITPW02152-TC25 and ITPW02152-TC40)
- Disposable gloves

Specimen collection and storage[5]

Fingerstick whole blood

Rub the target finger to stimulate blood flow. Clean the finger with an alcohol swab (Figure I.4) and leave it to dry. Pierce the skin of target finger with a sterile safety lancet. For the provided sterile safety lancet: a. Twist the protective cap more than 180° clockwise and remove it (see Figure I.5 for details); b. Place the lancet firmly on the side of the finger (avoid callus) to trigger it (see Figure I.6 for details). Gently press around the site of puncture to obtain a drop of blood (avoid excessive bleeding). Wipe away the first drop of blood with a sterile gauze pad (see Figure I.7 for details) and allow a new drop of blood to form. Collect the blood specimen with the dropper provided. Gently squeeze the bulb of the dropper and touch the tip to a drop of blood. Gently release the bulb to draw up the blood past the tip of the dropper (see Figure 1a and I.8 for details).

Venous whole blood

Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA, heparin sodium or sodium citrate) according to standard venous blood sampling process. Other anticoagulants may lead to incorrect results. Store whole blood specimen at 2-8°C for up to 3 days if it is not used immediately after being sampled. Do not freeze whole blood specimen. Before testing, gently shake the collection tube to obtain a homogeneous specimen.

Serum

Collect whole blood specimen into a collection tube which contains no anti- coagulant according to standard venous blood sampling process. Leave it to settle for 30 minutes for blood coagulation, then centrifuge at 3000rpm for at least 5 minutes to obtain the serum supernatant.

Plasma

Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA, heparin sodium or sodium citrate) according to standard venous blood sampling process. Gently invert the collection tube several times and leave it to settle for 30 minutes for blood coagulation, then centrifuge at 3000rpm for at least 5 minutes to obtain the plasma supernatant.

Notes:

- Serum or plasma specimens must be stored at 2-8°C for up to 7 days from time of draw. Store at -18°C or below for long time storage. Multiple freeze- thaw cycles should be avoided (3 times at most). Frozen specimens must be equilibrated to room temperature (10-30°C) before testing.
- Serum or plasma specimen containing precipitate may lead to invalid results. Centrifuge the specimen and use the supernatant for the test.

Test procedure

01. Do not open the pouch until ready to perform the test. Use the test immediately after opening the pouch;
02. Equilibrate all reagents and specimens to room temperature (10-30°C) before use;
03. Put on gloves;
04. Unseal the foil pouch and place the cassette on a clean, dry and level surface;
05. Write a client identifier on the test;
06. Clean the finger with an alcohol swab and leave it to dry;
07. Twist the lancet cap clockwise more than 180° and remove it;
08. Place the lancet firmly on the side of the finger (avoid callus) to trigger it;
09. Gently massage around the bleeding point. Wipe away the first drop of blood;
10. Gently squeeze the bulb of the dropper and touch the tip to a drop of blood.Release the bulb to collect blood past the tip of the dropper;
11. Add **1 drop** of the specimen (whole blood, serum or plasma) by gently squeezing the bulb of the dropper (or 30μL by transfer pipette) into the **"S"** well of the cassette;
12. Immediately add **1 drop (50μL)** of sample diluent into the **"S"** well;
13. Wait and interpret the result at 15 minutes, but not after 20 minutes.

⚠ Caution:

- Always apply specimen with a new and clean dropper or pipette tip to avoid cross contamination.
- Negative results cannot rule out the possibility of exposure to or infection with HIV-1 or HIV-2 viruses.

Result interpretation

Negative: If a purplish red band appears on the **"C"** area only, it indicates a negative result.

Positive: If purplish red bands appear at both the **"T"** area (even though very weak) and the **"C"** area, it indicates a positive result;

Invalid 1: If a purplish red band appears at the **"T"** area only, it indicates an invalid result. Repeat the test. Contact the supplier if the control band remains invisible at the **"C"** area;

Invalid 2: If a purplish red band does not appear at either the **"C"** area or the "T" area, it indicates an invalid result. Repeat the test. Contact the supplier if the control band remains invisible at the **"C"** area.

Performance characteristics

The performance of *ONE STEP Anti-HIV (1&2) Test* has been evaluated by testing specimens from blood donors, hospitalized patients and commercial seroconversion panels.

Sensitivity

Performance on HIV positive specimens

A study was performed using specimens with confirmed HIV positive status and tested by *ONE STEP Anti-HIV (1&2) Test*.

Table 2 Performance on HIV positive specimens

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

40 plasma specimens with known HIV-1 non-B subtypes were tested with the *ONE STEP Anti-HIV (1&2) Test*. All specimens show positive results with clear test bands.

Table 3 Test results on specimens with known HIV-1 non-B subtypes.

HIV subtype	n	ONE STEP Anti-HIV (1&2) Test	
		Positive	Negative
A	5	5	0
C	5	5	0
D	5	5	0
F	5	5	0
G	4	4	0
H	3	3	0
J	3	3	0
K	3	3	0
O	3	3	0
CRF01_AE	2	2	0
Total	38	38	0

Performance on commercial seroconversion panels [6]

ONE STEP Anti-HIV (1&2) Test shows good sensitivity in early infection on available commercial seroconversion panels.

Specificity

Table 4 Performance on HIV negative specimens

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

Table 5 Performance on cross-reactive specimens

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

Precision

3 lots of *ONE STEP Anti-HIV (1&2) Test* were tested at three different labs by both professional and non-professional operators to analyze the reproducibility and repeatability of the product.
All HIV negative specimens were non-reactive in the test; the difference between results of each medium/weak positive specimen obtained during the 5-day reproducibility study or the 20-day repeatability study was no greater than 2 intensity degrees according to the 11-degree internal QC system. *ONE STEP Anti-HIV (1&2) Test* showed good reproducibility and repeatability in the precision studies.

Specimen type

Sensitivity obtained from paired whole blood/plasma specimens obtained from 100 anti-HIV positive patients was 100% (see Table 2).
Specificity obtained from 500 whole blood specimens of blood donors was 100% (see Table 4).

Table 6 Serum and plasma comparison (HIV negative specimens)

	EDTA plasma	Heparin plasma	Citrate plasma	serum
Negative	25	25	25	25
Positive	0	0	0	0
Specificity	100%	100%	100%	100%

Table 7 Serum and plasma comparison (HIV positive specimens)

	EDTA plasma	Heparin plasma	Citrate plasma	serum
Negative	0	0	0	0
Positive	25	25	25	25
Specificity	100%	100%	100%	100%

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

Table 8 Venous and fingerstick whole blood comparison

Specimens Types	HIV positive specimens		HIV negative specimens	
	Venous whole blood	Fingerstick whole blood	Venous whole blood	Fingerstick whole blood
Negative	0	0	25	25
Positive	26	26	0	0
Concordance rate	100%	100%	100%	100%

According to Table 6, Table 7 and Table 8, ONE STEP Anti-HIV (1&2) Test can give consistent test results on serum, plasma, venous whole blood and fingerstick whole blood specimens.

Limitations ⚠

- The kit is designed to detect antibodies against HIV-1 and HIV-2 in human serum, plasma, and whole blood. Specimens other than those specified may not supply accurate results and the device will not notify this kind of misuse to the user.
- The intensity of the test band does not necessarily correlate to the titer of antibody in the specimen.
- The presence of the control band only indicates the flow of the conjugate.
- When a specimen containing high concentration of antibodies to HIV-1 or HIV-2 is tested on the device, the control band could be absent due to the test principle. In this case, please perform further analysis according to the section **"Result interpretation".**
- As this product is intended to detect antibodies against HIV from individuals, clinical diagnosis of HIV infection or AIDS should not be made only based on the results of the product.
- A negative result should not exclude the possibility of infection caused by HIV-1 or HIV-2. A negative result can also occur in the following circumstances:
  - Recently acquired HIV infection.
  - Low antibody levels (e.g., early seroconversion specimens) which are below the detection limit of the test.
  - HIV antibodies in the patient that do not react with specific antigens utilized in the assay configuration. In exceptional cases this may lead to an observation of negative results.
  - Specimens are not properly stored.
  - High concentrations of a particular analyte.
  - Recently discovered type or subtype of HIV.
- For reasons above, care should be taken in interpreting negative results. Other clinical data (e.g., symptoms or risk factors) should be used in conjunction with the test results.
- Positive specimens should be retested using another method and the results should be evaluated considering the overall clinical evaluation before a diagnosis is made.
- The product is not validated on specimens from infants, children, or patients on antiviral treatment.
- Use of hemolytic specimens, rheumatoid factors-containing specimens,hyperlipemia specimens or icteric specimens may lead to impairment to the test result.
- Only specimens with good fluidity and without hemolysis can be used with this test.

References

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: 1352-7.
3. World Health Organization. Laboratory biosafety manual. Geneva. World Health Organization, 2004.
4. National Committee for Clinical Laboratory Standards. Protection of laboratory workers from infectious disease transmitted by blood, body fluids, and tissue: Tentative guideline. NCCLS Document M29-T. Villanova, PA.: NCCLS, 1989.
5. Clinical and Laboratory Standards Institute. Procedures and Devices for collection of Diagnostic Capillary Blood Specimens, Approved Standard-Sixth Edition H4-A6.
6. Evaluation report, German Red Cross. July 2015.

Key to symbols used

	CAUTION		TEMPERATURE LIMITATION (2~30°C)
	KEEP AWAY FROM SUNLIGHT		KEEP DRY
	MANUFACTURER	IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
LOT	BATCH CODE	REF	CATALOGUE NUMBER
	CONSULT INSTRUCTIONS FOR USE		USE-BY DATE
	DO NOT REUSE		DO NOT USE IF PACKAGE IS DAMAGED
	CONTAINS SUFFICIENT FOR (N) TESTS	STERILE R	STERILIZED USING IRRADIATION

InTec PRODUCTS, INC.
332 Xinguang Road, Xinyang Industrial Area,
Haicang, 361022, Xiamen, Fujian, P.R. China
Tel: +86 592 6807188
Website: www.intecasi.com
Email: intecproducts@asintec.com

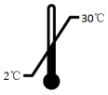
Advanced Quality

01.05.03.1307-190901
Release date: 20190430

ONE STEP Anti-HIV (1&2) Test

Colloidal Gold (Whole blood/serum/plasma)

Key to symbols used

	CAUTION		TEMPERATURE LIMITATION (2~30℃)
	KEEP AWAY FROM SUNLIGHT		KEEP DRY
	MANUFACTURER	IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
LOT	BATCH CODE	REF	CATALOGUE NUMBER
	CONSULT INSTRUCTIONS FOR USE		USE-BY DATE
	DO NOT REUSE		DO NOT USE IF PACKAGE IS DAMAGED
	CONTAINS SUFFICIENT FOR 〈N〉 TESTS	STERILE R	STERILIZED USING IRRADIATION

InTec PRODUCTS, INC.
332 Xinguang Road, Xinyang Ind. Area,
Haicang, Xiamen, 361022, P.R. China
Tel: +86 592 6807100
Website: www.intecasi.com
Email: intecproducts@asintec.com

ADVANCED QUALITY

REF ITPW02152-TC25
ITPW02152-TC40
ITPW02153-TC40
ITPW02153-TC40SA

ONE STEP Anti-HIV (1&2) Test

For *in vitro* diagnostic use only. IVD

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 (venous and fingerstick), serum or plasma specimens in adults. This test is intended for use by healthcare professionals and trained healthcare workers as an aid in the diagnosis of HIV infection.

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 and presents the result at 15 minutes, but not after 20 minutes.

Test Principle

The test band region on the nitrocellulose membrane is pre-coated with recombinant HIV antigen (containing predominant epitope of gp41, gp120 of HIV-1 and predominant epitope of gp36 of HIV-2), and the control band 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-1 and predominant epitope of gp36 of HIV-2) 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 band region, forming a test band.
A negative specimen will not produce a test band due to the absence of colloidal gold conjugate/HIV antibody complex. To ensure assay validity, a purplish red control band in the control region will appear regardless of the test result.
The assay is only valid when the control band appears.

Storage conditions and stability

The shelf life of the *ONE STEP Anti-HIV (1&2) Test,* including the sample diluent, is 24 months from date of manufacture. Product shall be stored at 2-30°C. Test cassette should be used immediately upon opening the foil pouch. Sample diluent should be stored capped at 2-30°C and used within 8 weeks after opening.

⚠ Warnings and precautions[3-4]

The warnings and precautions are included, but not limited to the following:

[Warnings]

- This product is for in vitro diagnosis of the infection of HIV only, other diseases cannot be analyzed with any component of this kit.
- All specimens with positive results must be confirmed using an appropriate test such as immunoblot assay or equivalent.
- 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 quantity used in this kit is small, however, when disposing sodium azide containing materials, flush with relatively large quantities of water to prevent metal azide build up in plumbing systems.

[Precautions]

- Wear gloves during the entire testing process.
- Do not use expired reagents or test cassettes.
- Do not use accessories if the seal or package is broken.
- Do not use test cassette if the foil pouch is damaged or the seal is broken.
- Do not use the provided sterile safety lancets if the cap is already pulled off before use.
- Do not reuse the accessories. All the accessories are for single use.
- Do not reuse the cassette. Each cassette enclosed in a foil pouch is only for single use.
- Do not pipette by mouth.
- Do not eat or smoke while handling specimens.
- Do not store the specimen in dropper , it is only used for specimen collection.
- Do not use pooled specimens or specimens other than specified (i.e. saliva, urine).
- Do not interchange reagents among kits of different batch number or even products.
- Do not perform the test in an environment which leads to rapid evaporation (e.g. ＞40°C and ＜40% relative humidity, close to a running fan or air conditioner).
- Ensure the specimen is added correctly prior to the addition of sample diluent.
- Avoid contact between the "S" well of the cassette and diluent bottle to prevent contamination of the diluent.
- Clean and disinfect all the areas that may be contaminated by spills of specimens or reagents with appropriate disinfectant.
- Decontaminate and dispose of all specimens, reagents, accessories and other potentially contaminated materials as infectious wastes in a biohazard container. Used lancet should be disposed of in a sharps bin.

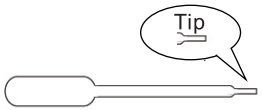
Reagent and materials provided

Table 1 Reagent and materials provided

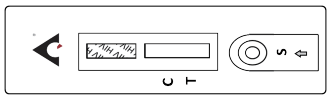
Component	25 tests (ITPW02152-TC25)	40 tests (ITPW02152-TC40)	40 tests (ITPW02153-TC40/ ITPW02153-TC40SA)
Test cassette	1×25 pieces	1×40 pieces	1×40 pieces
Dropper	1×25 pieces	1×40 pieces	1×40 pieces
Desiccant	1×25 pieces	1×40 pieces	1×40 pieces
Sample diluent	2mL×3 bottles	2mL×4 bottles	2mL×4 bottles
Sterile safety lancet	Not provided	Not provided	2×20 pieces
Alcohol swab	Not provided	Not provided	1×40 pieces
Package insert	1×1 piece	1×1 piece	1×1 piece

Preparation

1a. Unseal the foil pouch. The components provided with products of ITPW02153-TC40 and ITPW02153-TC40SA are as below.



Dropper



Cassette

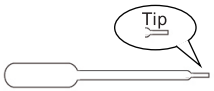

Desiccant

Alcohol swab


Safety lancet


Sample diluent

1b. Unseal the foil pouch. The components provided with products of ITPW02152-TC25 and ITPW02152-TC40 are as below.



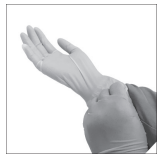
Dropper

Cassette


Desiccant


Sample diluent

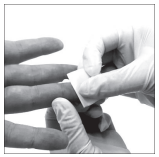
2. Put on gloves.



3. Write a client identifier on the test.

I. Fingerstick whole blood

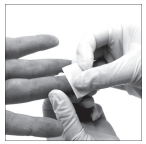
4. Clean the finger with an alcohol swab and leave it to dry.



5. Twist the lancet cap clockwise, more than 180° and remove it.

6. Place the lancet firmly on the side of the finger (avoid callus) to trigger it.

7. Gently massage around the bleeding point.Wipe away the first drop of blood.



8. Gently squeeze the bulb of the dropper and touch the tip to a drop of blood. Release the bulb to collect blood past the tip of the dropper.

9. Add **1 drop** (30µl) of whole blood by gently squeezing the bulb of the provided dropper into the **"S"** Well.

10. Immediately add **1 drop** (50µl) of sample diluent into the **"S"** Well.

11. Wait and interpret the result at 15 min, but not after 20 min.

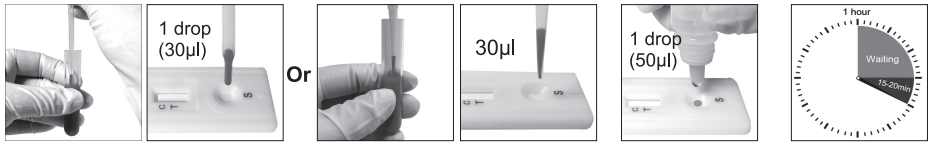
II. Venous whole blood

4a. Add **1 drop** (30µl) of whole blood by gently squeezing the bulb of the provided dropper into the **"S"** Well.

4b. Add **30µl** (1 drop) of whole blood using the transfer pipette into the **"S"** Well.

5. Immediately add **1 drop** (50µl) of sample diluent into the **"S"** Well .

6. Wait and interpret the result at 15 min, but not after 20 min.



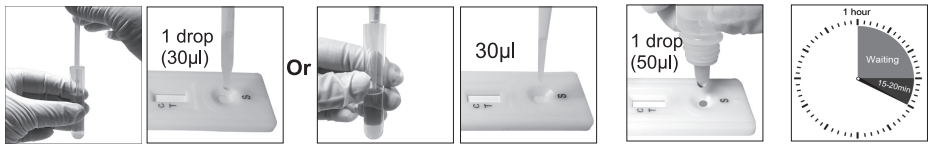
III. Serum/plasma

4a. Add **1 drop** (30µl) of specimen by gently squeezing the bulb of the provided dropper into the **"S"** Well.

4b. Add **30µl** (1 drop) of specimen using the transfer pipette into the **"S"** Well.

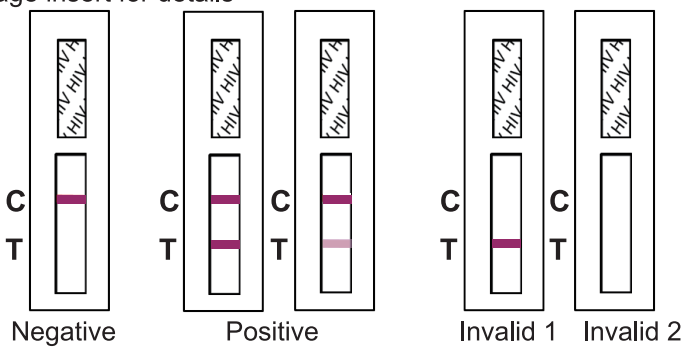
5. Immediately add **1 drop** (50µl) of sample diluent into the **"S"** Well .

6. Wait and interpret the result at 15 min, but not after 20 min.



Result interpretation

See package insert for details



Materials required but not provided

- Timer or stopwatch
- Blood sampling tools (sterile gauze pad, venous puncture device, collection tube with EDTA/heparin sodium/sodium citrate for whole blood or plasma, collection tube with no anticoagulant for serum.)
- Biohazard waste container and sharps bin
- Sterile safety lancet and alcohol swab (product code ITPW02152-TC25 and ITPW02152-TC40)
- Disposable gloves

Specimen collection and storage[5]

Fingerstick whole blood

Rub the target finger to stimulate blood flow. Clean the finger with an alcohol swab (Figure I.4) and leave it to dry. Pierce the skin of target finger with a sterile safety lancet. For the provided sterile safety lancet: a. Twist the protective cap more than 180° clockwise and remove it (see Figure I.5 for details); b. Place the lancet firmly on the side of the finger (avoid callus) to trigger it (see Figure I.6 for details). Gently press around the site of puncture to obtain a drop of blood (avoid excessive bleeding). Wipe away the first drop of blood with a sterile gauze pad (see Figure I.7 for details) and allow a new drop of blood to form. Collect the blood specimen with the dropper provided. Gently squeeze the bulb of the dropper and touch the tip to a drop of blood. Gently release the bulb to draw up the blood past the tip of the dropper (see Figure 1a and I.8 for details).

Venous whole blood

Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA, heparin sodium or sodium citrate) according to standard venous blood sampling process. Other anticoagulants may lead to incorrect results. Store whole blood specimen at 2-8°C for up to 3 days if it is not used immediately after being sampled. Do not freeze whole blood specimen. Before testing, gently shake the collection tube to obtain a homogeneous specimen.

Serum

Collect whole blood specimen into a collection tube which contains no anti-coagulant according to standard venous blood sampling process. Leave it to settle for 30 minutes for blood coagulation, then centrifuge at 3000rpm for at least 5 minutes to obtain the serum supernatant.

Plasma

Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA, heparin sodium or sodium citrate) according to standard venous blood sampling process. Gently invert the collection tube several times and leave it to settle for 30 minutes for blood coagulation, then centrifuge at 3000rpm for at least 5 minutes to obtain the plasma supernatant.

Notes:

- Serum or plasma specimens must be stored at 2-8°C for up to 7 days from time of draw. Store at -18°C or below for long time storage. Multiple freeze-thaw cycles should be avoided (3 times at most). Frozen specimens must be equilibrated to room temperature (10-30°C) before testing.
- Serum or plasma specimen containing precipitate may lead to invalid results. Centrifuge the specimen and use the supernatant for the test.

Test procedure

01. Do not open the pouch until ready to perform the test. Use the test immediately after opening the pouch;
02. Equilibrate all reagents and specimens to room temperature (10-30°C) before use;
03. Put on gloves;
04. Unseal the foil pouch and place the cassette on a clean, dry and level surface;
05. Write a client identifier on the test;
06. Clean the finger with an alcohol swab and leave it to dry;
07. Twist the lancet cap clockwise more than 180° and remove it;
08. Place the lancet firmly on the side of the finger (avoid callus) to trigger it;
09. Gently massage around the bleeding point. Wipe away the first drop of blood;
10. Gently squeeze the bulb of the dropper and touch the tip to a drop of blood. Release the bulb to collect blood past the tip of the dropper;
11. Add **1 drop** of the specimen (whole blood, serum or plasma) by gently squeezing the bulb of the dropper (or 30µl by transfer pipette) into the "**S**" well of the cassette;
12. Immediately add **1 drop** (50µl) of sample diluent into the "**S**" well;
13. Wait and interpret the result at 15 minutes, but not after 20 minutes.

⚠ **Caution:**

- Always apply specimen with a new and clean dropper or pipette tip to avoid cross contamination.
- Negative results cannot rule out the possibility of exposure to or infection with HIV-1 or HIV-2 viruses.

Result interpretation

Negative: If a purplish red band appears on the "**C**" area only, it indicates a negative result.

Positive: If purplish red bands appear at both the "**T**" area (even though very weak) and the "**C**" area, it indicates a positive result;

Invalid 1: If a purplish red band appears at the "**T**" area only, it indicates an invalid result. Repeat the test.
Contact the supplier if the control band remains invisible at the "**C**" area;

Invalid 2: If a purplish red band does not appear at either the "**C**" area or the "**T**" area, it indicates an invalid result. Repeat the test.
Contact the supplier if the control band remains invisible at the "**C**" area.

Performance characteristics

The performance of *ONE STEP Anti-HIV (1&2) Test* has been evaluated by testing specimens from blood donors, hospitalized patients and commercial seroconversion panels.

Sensitivity

Performance on HIV positive specimens

A study was performed using specimens with confirmed HIV positive status and tested by *ONE STEP Anti-HIV (1&2) Test.*

Table 2 Performance on HIV positive specimens

Specimen Types	Positive by *ONE STEP Anti-HIV (1&2) Test*	Total number of tested specimens	Sensitivity
HIV-1 positive plasma specimens	260	260	100% 95%CI (98.59-100.00)
HIV-1 positive plasma of different subtypes (non-B) specimens	40	40	100% 95%CI (91.19-100.00)

Paired HIV-1 positive venous whole blood specimens	100	100	100% 95%CI (96.38-100.00)
Paired HIV-1 positive plasma specimens	100	100	100% 95%CI (96.38-100.00)
HIV-2 positive plasma specimens	100	100	100% 95%CI (96.38-100.00)

40 plasma specimens with known HIV-1 non-B subtypes were tested with the *ONE STEP Anti-HIV (1&2) Test*. All specimens show positive results with clear test bands.

Table 3 Test results on specimens with known HIV-1 non-B subtypes.

HIV subtype	n	ONE STEP Anti-HIV (1&2) Test	
		Positive	Negative
A	5	5	0
C	5	5	0
D	5	5	0
F	5	5	0
G	4	4	0
H	3	3	0
J	3	3	0
K	3	3	0
O	3	3	0
CRF01_AE	2	2	0
Total	40	40	0

Performance on commercial seroconversion panels [6]
ONE STEP Anti-HIV (1&2) Test shows good sensitivity in early infection on available commercial seroconversion panels.

Specificity

Table 4 Performance on HIV negative specimens

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

Table 5 Performance on cross-reactive specimens

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

Precision
3 lots of *ONE STEP Anti-HIV (1&2) Test* were tested at three different labs by both professional and non-professional operators to analyze the reproducibility and repeatability of the product.
All HIV negative specimens were non-reactive in the test; the difference between results of each medium/weak positive specimen obtained during the 5-day reproducibility study or the 20-day repeatability study was no greater than 2 intensity degrees according to the 11-degree internal QC system. *ONE STEP Anti-HIV (1&2) Test* showed good reproducibility and repeatability in the precision studies.

Specimen type
Sensitivity obtained from paired whole blood/plasma specimens obtained from 100 anti-HIV positive patients was 100% (see Table 2).
Specificity obtained from 500 whole blood specimens of blood donors was 100% (see Table 4).

Table 6 Serum and plasma comparison (HIV negative specimens)

	EDTA plasma	Heparin plasma	Citrate plasma	serum
Negative	25	25	25	25
Positive	0	0	0	0
Specificity	100%	100%	100%	100%

Table 7 Serum and plasma comparison (HIV positive specimens)

	EDTA plasma	Heparin plasma	Citrate plasma	serum
Negative	0	0	0	0
Positive	25	25	25	25
Sensitivity	100%	100%	100%	100%

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

Table 8 Venous and fingerstick whole blood comparison

	HIV positive specimens		HIV negative specimens	
	Venous whole blood	Fingerstick whole blood	Venous whole blood	Fingerstick whole blood
Negative	0	0	25	25
Positive	26	26	0	0
Concordance rate	100%	100%	100%	100%

According to Table 6, Table 7 and Table 8, ONE STEP Anti-HIV (1&2) Test can give consistent test results on serum, plasma, venous whole blood and fingerstick whole blood specimens.

Limitations ⚠

- The kit is designed to detect antibodies against HIV-1 and HIV-2 in human serum, plasma, and whole blood. Specimens other than those specified may not supply accurate results and the device will not notify this kind of misuse to the user.
- The intensity of the test band does not necessarily correlate to the titer of antibody in the specimen.
- The presence of the control band only indicates the flow of the conjugate.
- When a specimen containing high concentration of antibodies to HIV-1 or HIV-2 is tested on the device, the control band could be absent due to the test principle. In this case, please perform further analysis according to the section **"Result interpretation"**.
- As this product is intended to detect antibodies against HIV from individuals, clinical diagnosis of HIV infection or AIDS should not be made only based on the results of the product.
- A negative result should not exclude the possibility of infection caused by HIV-1 or HIV-2. A negative result can also occur in the following circumstances:
  - Recently acquired HIV infection.
  - Low antibody levels (e.g., early seroconversion specimens) which are below the detection limit of the test.
  - HIV antibodies in the patient that do not react with specific antigens utilized in the assay configuration. In exceptional cases this may lead to an observation of negative results.
  - Specimens are not properly stored.
  - High concentrations of a particular analyte.
  - Recently discovered type or subtype of HIV.
- For reasons above, care should be taken in interpreting negative results. Other clinical data (e.g., symptoms or risk factors) should be used in conjunction with the test results.
- Positive specimens should be retested using another method and the results should be evaluated considering the overall clinical evaluation before a diagnosis is made.
- The product is not validated on specimens from infants, children, or patients on antiviral treatment.
- Use of hemolytic specimens, rheumatoid factors-containing specimens, hyperlipemia specimens or icteric specimens may lead to impairment to the test result.
- Only specimens with good fluidity and without hemolysis can be used with this test.

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