WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: ONE STEP Anti - HIV (1&2) Test
WHO reference number: PQDx0372-017-00

ONE STEP Anti - HIV (1&2) Test with product codes **ITPW02152-TC40, ITPW02152-TC25, ITPW02153-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 of May 2019.

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

	Date	Outcome
Prequalification listing	17-05-2019	Listed
Dossier review		N/A
Site inspection(s) of quality management system	27-08-2018 to 30-08-2018	MR
Product performance evaluation	Fourth quarter of 2018	MR

MR: Meet Requirements
N/A: Not Applicable

Intended use:

According to the manufacturer *"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 manufacturer "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 (product code ITPW02152-TC25)**	**40 tests (product code (ITPW02152-TC40)**	**40 tests (product code (ITPW02153-TC40)**
Test cassette	1×25 pieces	1×40 pieces	1×40 pieces
Dropper	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	1×40 pieces
Alcohol swab	Not provided	Not provided	1×40 pieces
Package insert	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, **ONE STEP Anti‑HIV (1&2) Test** was given priority for 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 **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 5 March 2019.

Commitments for prequalification:

1. InTec gives a commitment to WHO that supplemental performance studies to demonstrate analytical specificity, which incorporate a clinically relevant concentration of target analyte near to the cut-off-value (COV) for the assay, will be completed by 31 March 2019 and that a copy of the summary study report will be provided to WHO by 29 April 2019.

2. InTec gives a commitment to WHO, that six monthly updates will be provided (starting on 1 July 2019) on the progress of the scheduled process re-validation with a summary outcome of every validation completed in every six-monthly period.

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 4 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 specimen, 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 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, control line on the test device (reagent control)
In-use stability of reagents	Sample diluent shall be used within 8 weeks after first open.

Limitations of the performance evaluation:

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

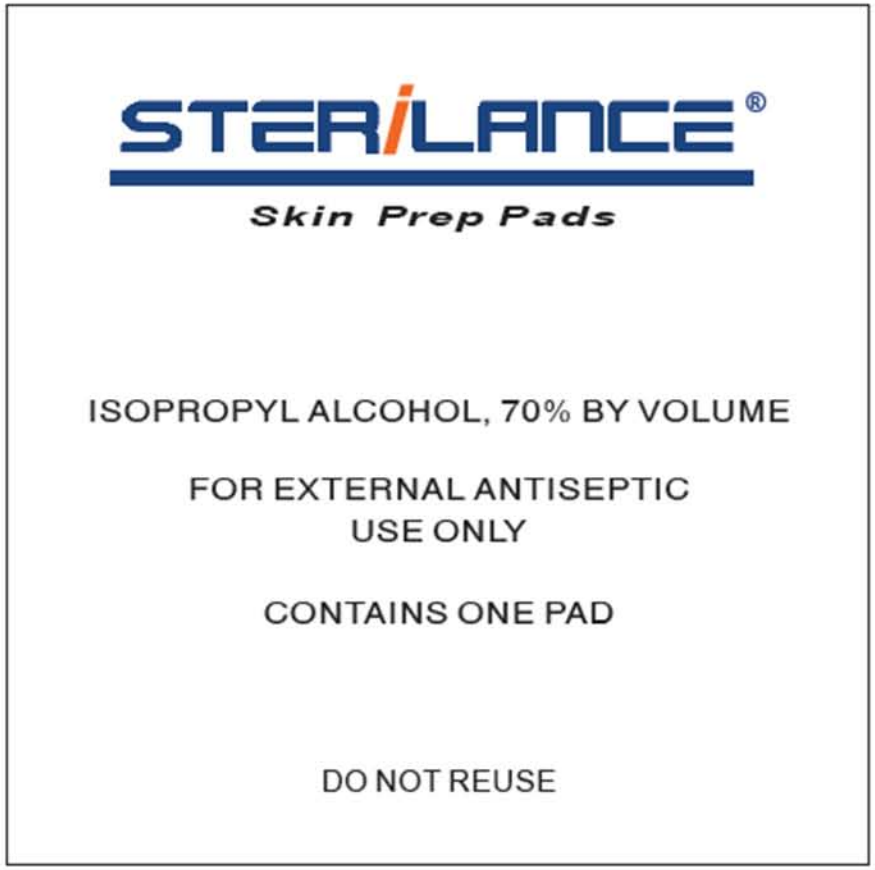
2. All positive specimens in the performance evaluation were positive for HIV-1, so the sensitivity of ONE STEP Anti-HIV (1&2) Test for the detection of HIV-2 could not be assessed.

Labelling

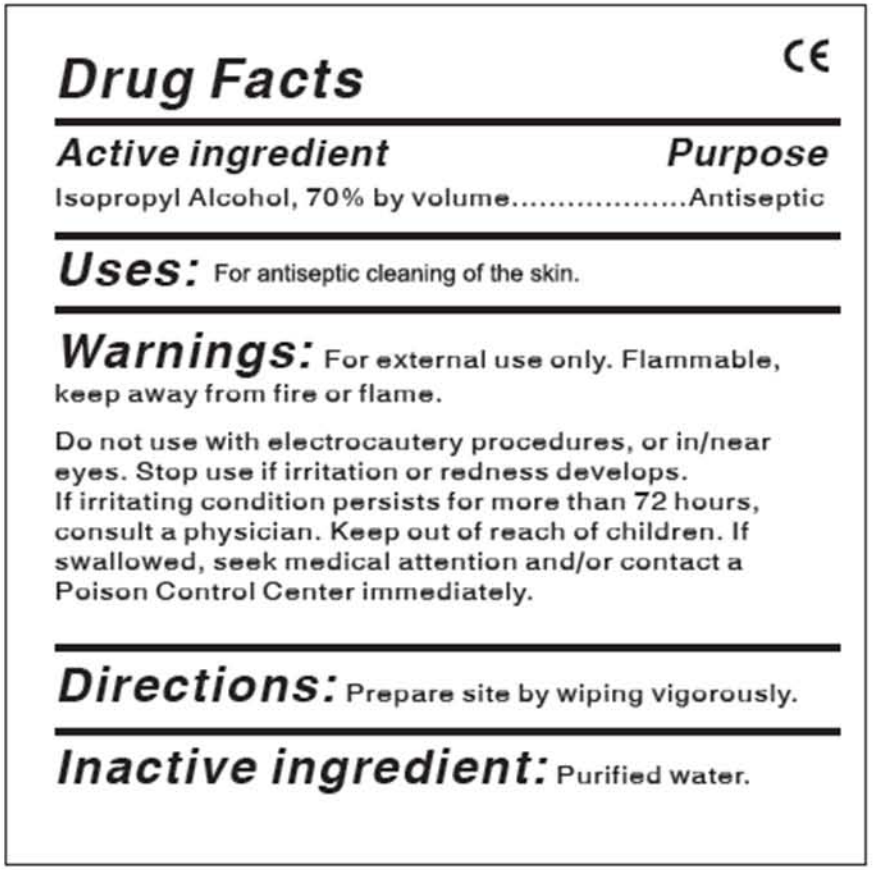
1. **Labels**
2. **Instructions for use**

1.0 labels

1.1.1 Alcohol swab front



1.1.2 Alcohol swab back



1.1.3 Secondary packaging for alcohol swabs

Alcohol swab

CE

Manufactured for InTec PRODUCTS, INC.
by SteriLancet Medical (Suzhou) Inc.

1.2 Secondary packaging for sterile safety lancet

Safety lancet CE 0197

Manufactured for InTec PRODUCTS, INC.
by SteriLancet Medical (Suzhou) Inc.

1.3.1 Box for ITPW02153-TC40

ITPW02153-TC40

235*155*62mm

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

HIV

InTec PRODUCTS, INC.

InTec PRODUCTS,INC.
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Xiamen,361022,p.R.China

Tel: (+86) 5926807100
Website: www.intecasi.com
Email: intecproducts@asintec.com

ONE STEP Anti-HIV（1&2）Test

1.3.2 Box for ITPW02152-TC25

ITPW02152-TC25
190*120*65mm

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

ADVANCED QUALITY IN MEDICAL DIAGNOSTICS
HIV

InTec PRODUCTS, INC.

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ONE STEP Anti-HIV (1&2) Test

1.3.3 Box for ITPW02152-TC40

ITPW02152-TC40

235*155*62mm

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

InTec PRODUCTS,INC.
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ONE STEP Anti-HIV (1&2) Test

1.4.1 Foil pouch front

InTec®

ONE STEP Anti-HIV (1&2) Test

Colloidal Gold (Whole Blood/Serum/Plasma)

HIV

ADVANCED QUALITY
IN MEDICAL DIAGNOSTICS

1.4.2 Foil pouch back

ONE STEP Anti-HIV (1&2) Test

REF

LOT

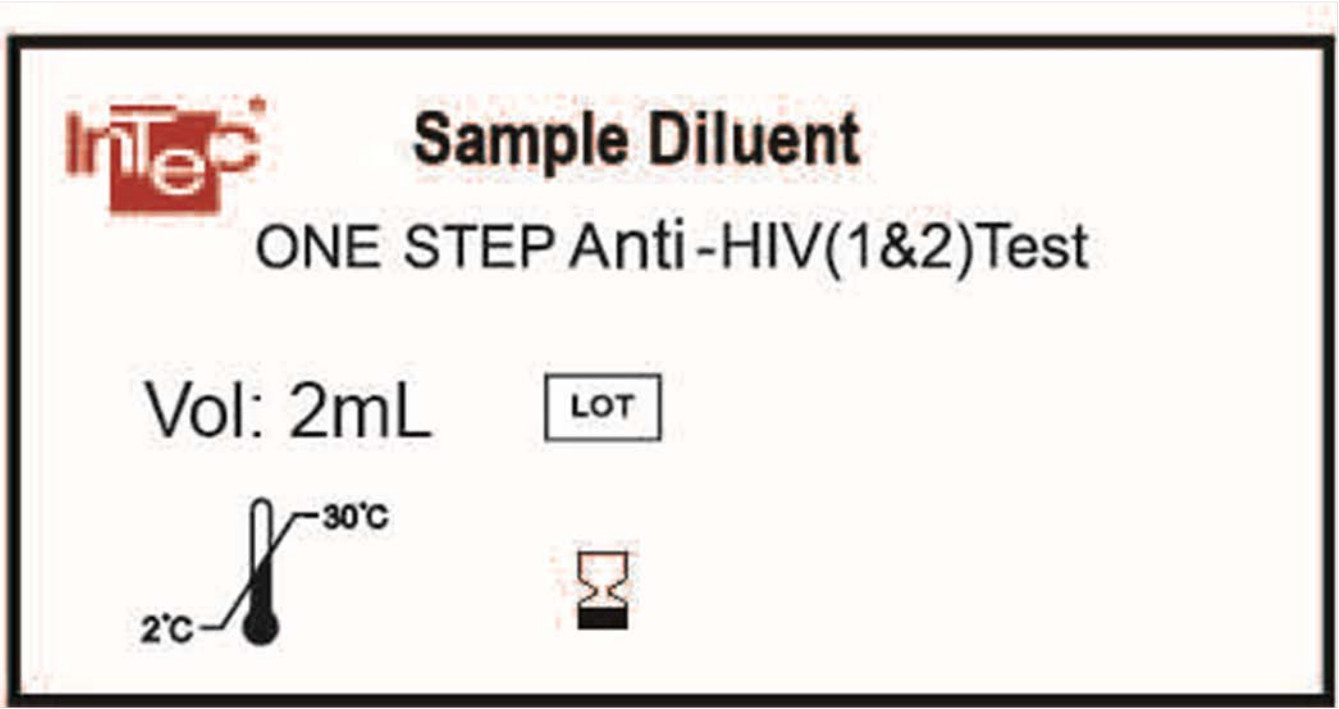
Contents

1 Test
1 Dropper
1 Desiccant

InTec PRODUCTS,INC.
332 Xinguang Road,Xinyang Ind.Area,Haicang,
Xiamen,361022,p.R.China
Tel: (+86) 5926807100
Website: www.intecasi.com
Email: intecproducts@asintec.com

IVD 2°C 30°C

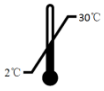
1.5 Sample diluent label



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		IN VITRO DIAGNOSTIC MEDICAL DEVICE
	BATCH CODE		CATALOGUE NUMBER
	CONSULT INSTRUCTIONS FOR USE		USE-BY DATE
	DO NOT REUSE		DO NOT USE IF PACKAGE IS DAMAGED
	CONTAINS SUFFICIENT FOR ‹N› TESTS		STERILIZED USING IRRADIATION

ADVANCED QUALITY™

REF ITPW02152-TC25
ITPW02152-TC40
ITPW02153-TC40

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 figerstick), 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 within 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

ONE STEP Anti-HIV (1&2) Test shall be stored at 2-30℃. Test cassette should be used immediately upon opening the foil pouch. Sample diluent should be stored capped at 2-30℃ 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 under environment which leads to rapid evaporation (e.g. ＞40℃ and ＜40% rH, 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" port of cassette and diluent bottle to prevent contamination of 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

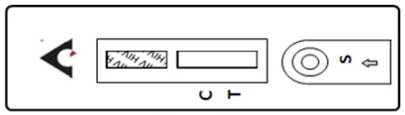
Table 1 Reagent and materials provided

Component	25 tests (ITPW02152-TC25)	40 tests (ITPW02152-TC40)	40 tests (ITPW02153-TC40)
Test cassette	1×25 pieces	1×40 pieces	1×40 pieces
Dropper	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	1×40 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 pouches. The components provided with products of ITPW02153-TC40 are as below.

Dropper

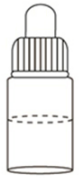


Cassette

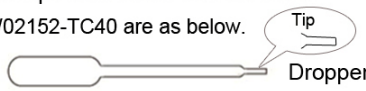

Desiccant

Alcohol swab

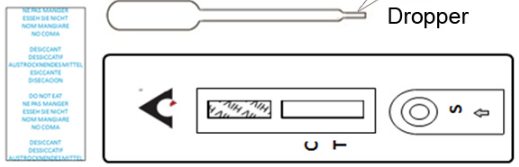

Safety lancet


Sample diluent

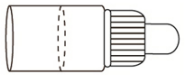
1b. Unseal the foil pouch. The components provided with products of ITPW02152-TC25 and ITPW02152-TC40 are as below.



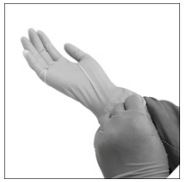
Dropper



Desiccant Cassette


Sample diluent

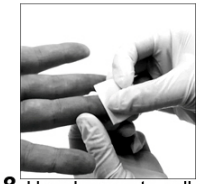
2. Wear gloves.



3. Mark the sample ID number.

I. *Fingerstick whole blood*

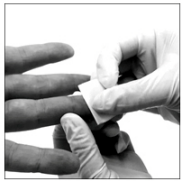
4. Clean the finger with alcohol swab and leave it to dry.



5. Twist the lancet cap for over 90° and remove it.

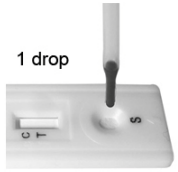
6. Place the lancet firmly on side of finger (avoid callus) to trigger it.

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



8. Use dropper to collect specimen. Gently squeeze and release bulb to collect blood past **tip** of dropper .

9. Add **1 drop** of the sample using the provided dropper into the port S.

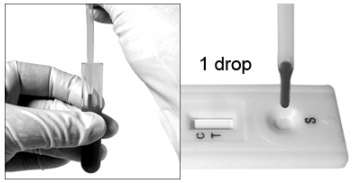


10. Add **1 drop** of sample diluent into port S immediately.

11. Wait and interpret the result between 15-20 minutes.

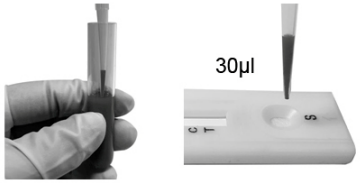
II. *Venous whole blood*

4a. Add **1 drop** of specimen using the provided dropper (Gently squeeze the bulb of the dropper for the blood) into port S.



Or

4b. Add 30µl of specimen using transfer pipette into port S.

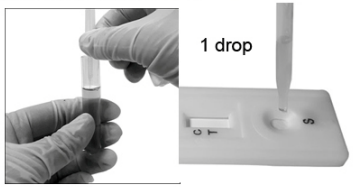


5. Add 1 **drop** of sample diluent into port S immediately.

6. Wait and interpret the result between 15-20 minutes.

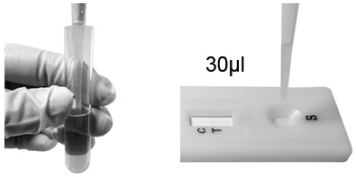
III. *Serum/plasma*

4a. Add **1 drop** of specimen using the provided dropper (Gently squeeze the bulb of the dropper for the blood) into port S.

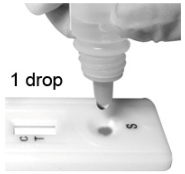


Or

4b. Add 30µl of specimen using transfer pipette into port S.



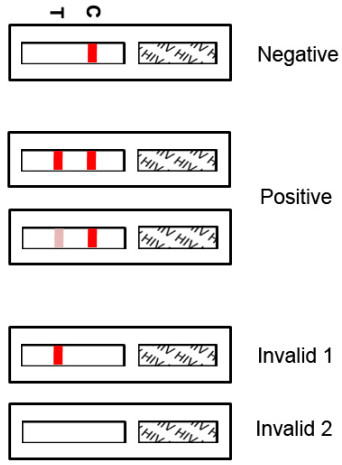
5. Add **1 drop** of sample diluent into port S immediately.



6. Wait and interpret the result between15-20 minutes.

Result interpretation

See the 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. Stick the skin of target finger with a sterile safety lancet (for the provided sterile safety lancet: a. Twist clockwise the protective cap and remove it , See Figure I.5 for details; b. Place the lancet firmly on side of 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 (Figure I.7). 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 of the blood. Gently release bulb to draw up blood past **tip** of dropper (Figure 1a and I.8).

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℃ 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 blood tube to obtain a homogeneous specimen.

Serum

Collect whole blood specimen into a collection tube contains no anticoagulant according to standard venous blood sampling process. Leave 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 for several times and leave 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 shall be stored at 2-8℃ 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 shall be equilibrated to room temperature (10-30℃) 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

1. Do not open the pouch until ready to perform a test. Use the test immediately after opening the pouch.
2. Equilibrate all reagents and specimens to room temperature (10-30℃) before use;
3. Unseal the foil pouch and put the cassette on a clean, dry and level surface;
4. Mark the specimen ID number on test cassette;
5. Add 1 drop of the specimen using the provided dropper (or 30μl by transfer pipette) into port "S" of the cassette;
6. Then add 1 drop of sample diluent into port "S" immediately;
7. Wait and interpret the result between 15-20 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: Purplish red band only appears on control band area indicates a negative result.

Positive: Purplish red bands appear at both the test band area (even though very weak) and the control band area indicates a positive result.

Invalid 1: A purplish red band appears only at the test band area of the cassette. Repeat the test. Contact the supplier if the control band remains invisible.

Invalid 2: Purplish red band appears at neither the control band area nor the test band area of the cassette. Repeat the test. Contact the supplier if the control band remains invisible.

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 [7]

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 test band does not necessarily correlate to the titer of antibody in specimen.
- The presence of the control band only indicates the flow of the conjugate.
- When a specimen contain high concentration of antibody 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 section of "**Test result and 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 levels of antibody (e.g., early seroconversion specimens) 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 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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