WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: Rapid Anti-HCV Test
WHO reference number: PQDx0371-017-00

Rapid Anti - HCV Test with product codes **ITPW01152-TC40, ITPW01152-TC25, ITPW01153-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 the 17th of May 2019.

Summary of WHO prequalification assessment for

	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	Third quarter of 2018	MR

MR: Meet Requirements
N/A: Not Applicable

Intended use:
According to the manufacturer "Rapid Anti-HCV Test is a colloidal gold enhanced, rapid immunochromatographic assay for qualitative detection of antibodies to hepatitis C virus (HCV) in human whole blood (venous and fingerstick), serum or plasma specimens in adults. The test is intended for healthcare professionals and trained healthcare workers to use as an aid for diagnosis of HCV infection".

Assay description:

According to the manufacturer "*Recombinant HCV antigen (containing Core, NS2, NS3, NS4, NS5 segments) and mouse anti-human IgG antibody conjugated to colloidal gold are embedded in the sample pad. If the specimen is positive, the HCV antibody in whole blood, serum or plasma specimen will combine with the colloidal gold conjugated recombinant HCV antigen and generate a complex. As the mixture moves along the test strip, the complex will be captured by the recombinant HCV antigen (containing Core, NS2, NS3, NS4, NS5 segments) immobilized on the membrane, forming a purplish red test band in the test region.*

A negative specimen will not form any test band due to the absence of colloidal gold conjugate/HCV antibody complex. Regardless if HCV antibodies exist in a specimen, the unbound gold marked protein will bind to the sheep anti-mouse IgG in the control band region and form a purplish red band.

The assay is only valid when the control band appears".

Test kit contents:

Component	**25 tests (product code ITPW01152-TC25)**	**40 tests (product code (ITPW01152-TC40)**	**40 tests (product code (ITPW01153-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, Rapid Anti - HCV Test was given priority for WHO prequalification assessment.

Product dossier assessment

In accordance with the WHO procedure for abridged prequalification assessment, **InTec PRODUCTS, INC** was not required to submit a product dossier for **Rapid Anti - HCV 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 of manufacture 308, Wengjiao Rd, Xinyang IND.AREA, Haicang, Xiamen, 361022, China.) of Rapid Anti-HCVTestinAugust, 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 schedules 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 Rapid Anti-HCV Testmeets WHO prequalification requirements.

Product performance evaluation

The **Rapid Anti-HCV Test** (InTec PRODUCTS, Inc) is a rapid, lateral flow immunochromatographic assay for the detection of antibodies to HCV in human serum/plasma and whole blood. A volume of 10 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. Reading of the results can be done visually.

The Advanced Quality Rapid Anti-HCV Test (InTec PRODUCTS, Inc) was evaluated by WHO in the 3rd quarter of 2018 at the Virus Reference Department, Public Health England, UK. From this evaluation, we drew the following conclusions:

In this limited evaluation on a panel of 466 plasma specimens, compared to the reference diagnostic algorithm (Ortho HCV ELISA Test System 3.0 with enhanced SAVe, Ortho Clinical Diagnostics, and Monolisa Anti-HCV Plus, Bio-Rad, in parallel; followed by Chiron RIBA HCV 3.0 Strip Immunoassay), the following performance characteristics were obtained:

Performance characteristics in comparison with an agreed reference standard		
	Initial (95% CI)	**Final (95% CI)**
Sensitivity % (N=151)	100% (95% CI 97.6-100%)	100% (95% CI 97.6-100%)
Specificity % (N=315)	99.7% (95% CI 98.8-100%)	99.7% (95% CI 98.8-100%)
Invalid rate %	0	
Inter-reader variability %	0	

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

Additional performance characteristics	
Sensitivity during seroconversion on 4 seroconversion panels in comparison with a benchmark assay (Ortho HCV 3.0 Enhanced SAVe [Ortho Clinical Diagnostics])	Seroconversion sensitivity index of -0.75, therefore detection is 0.75 specimens earlier than the benchmark assay
Analytical sensitivity on mixed titer panels in comparison with an agreed reference standard	20 of 20 specimens in the anti-HCV worldwide performance panel were correctly classified. 27 of 30 specimens in the low titer performance panels were correctly classified
Lot to lot variation on dilution panels	Acceptable

Key operational characteristics	
Validated specimen types (according to IFU)	Serum, plasma (EDTA, heparin sodium or sodium citrate), 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 opening

Labelling

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

1.0 labels

1.1.1 Alcohol swab front

STERILANCE®

Skin Prep Pads

ISOPROPYL ALCOHOL, 70% BY VOLUME

FOR EXTERNAL ANTISEPTIC
USE ONLY

CONTAINS ONE PAD

DO NOT REUSE

1.1.2 Alcohol swab back

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.

1.1.3 Secondary packaging for alcohol swabs

Alcohol swab

CE

LOT

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

1.2 Secondary packaging for sterile safety lancet

Safety lancet CE 0197

LOT

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

1.3.1 Box for ITPW01153-TC40

ITPW01153-TC40

235*155*62mm

C 0 M 0 Y 0 K 100

C 30 M 100 Y 100 K 0

C 0 M 30 Y 95 K 0

Distributor Information

测试卡纸盒盒贴（侧面）

Test Card Label (Left Side)

Font: Arial Type Size : 10 Line Spacing : 15

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

01.05.11.052-170701

1.3.2 Box for ITPW01152-TC25

ITPW01152-TC25

190*120*65mm

C 0 M 0 Y 0 K 100

C 30 M 100 Y 100 K 0

C 0 M 30 Y 95 K 0

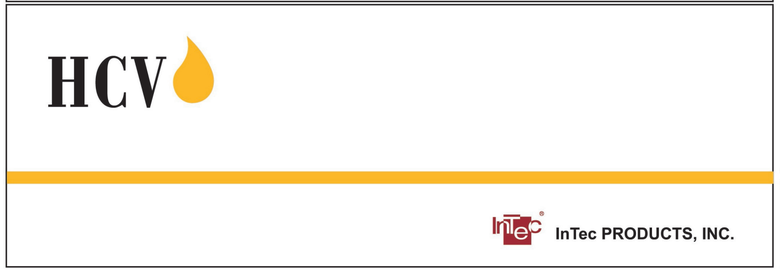
Distributor Information

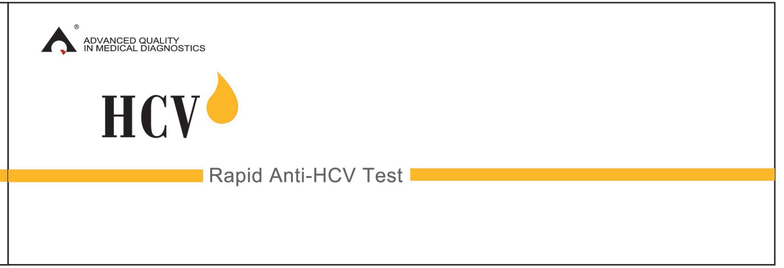
Font: Arial Type Size : 10 Line Spacing : 15

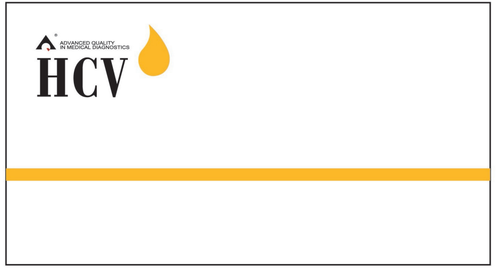
Size: 55*30mm Colour: C 0 M 0 Y 0 K 80

测试卡纸盒盒贴（侧面）

Test Card Label (Left Side)







1.3.3 Box for ITPW01152-TC40

ITPW01152-TC40

235*155*62mm

C 0 M 0 Y 0 K 100

C 30 M 100 Y 100 K 0

C 0 M 30 Y 95 K 0

Distributor Information

Font: Arial Type Size : 10 Line Spacing : 15

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

测试卡纸盒盒贴（侧面）

Test Card Label (Left Side)

HCV

InTec PRODUCTS, INC.

ADVANCED QUALITY IN MEDICAL DIAGNOSTICS

HCV

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

ADVANCED QUALITY IN MEDICAL DIAGNOSTICS

HCV

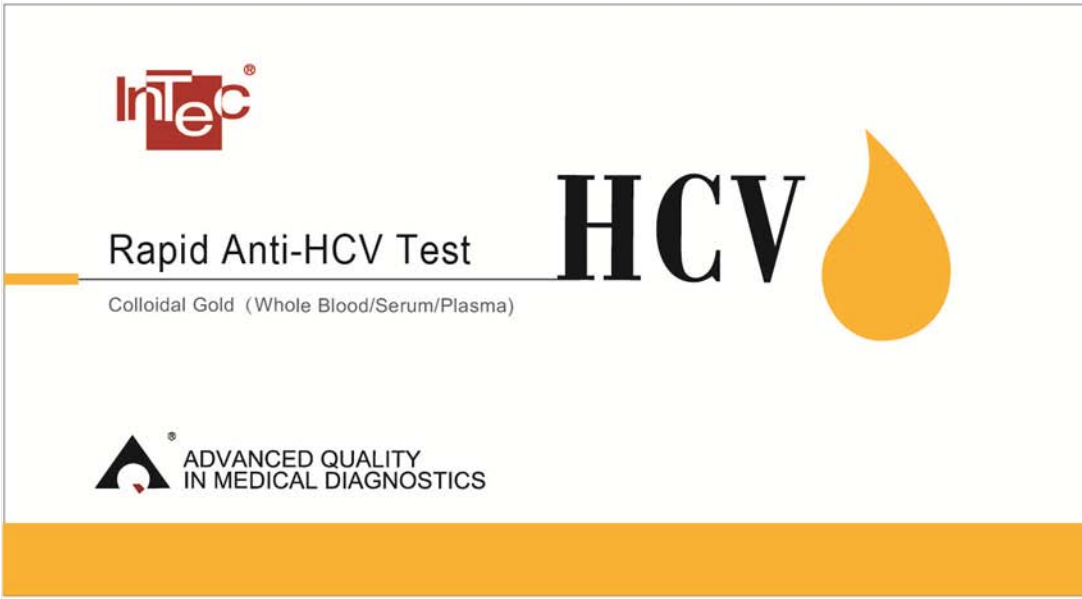
Rapid Anti-HCV Test

ADVANCED QUALITY IN MEDICAL DIAGNOSTICS

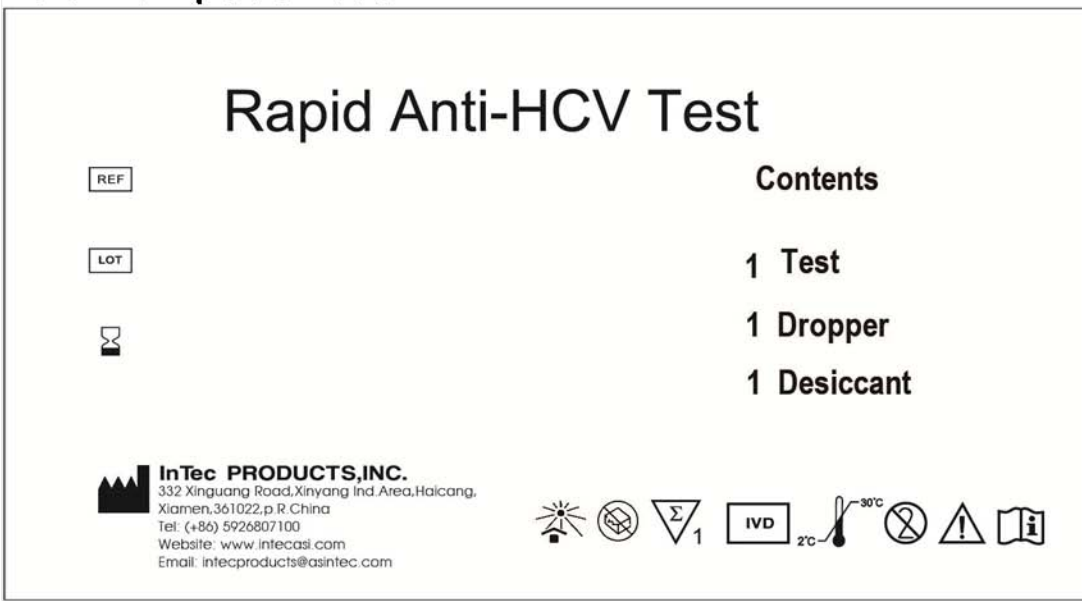
HCV

01.05.11.050-170701

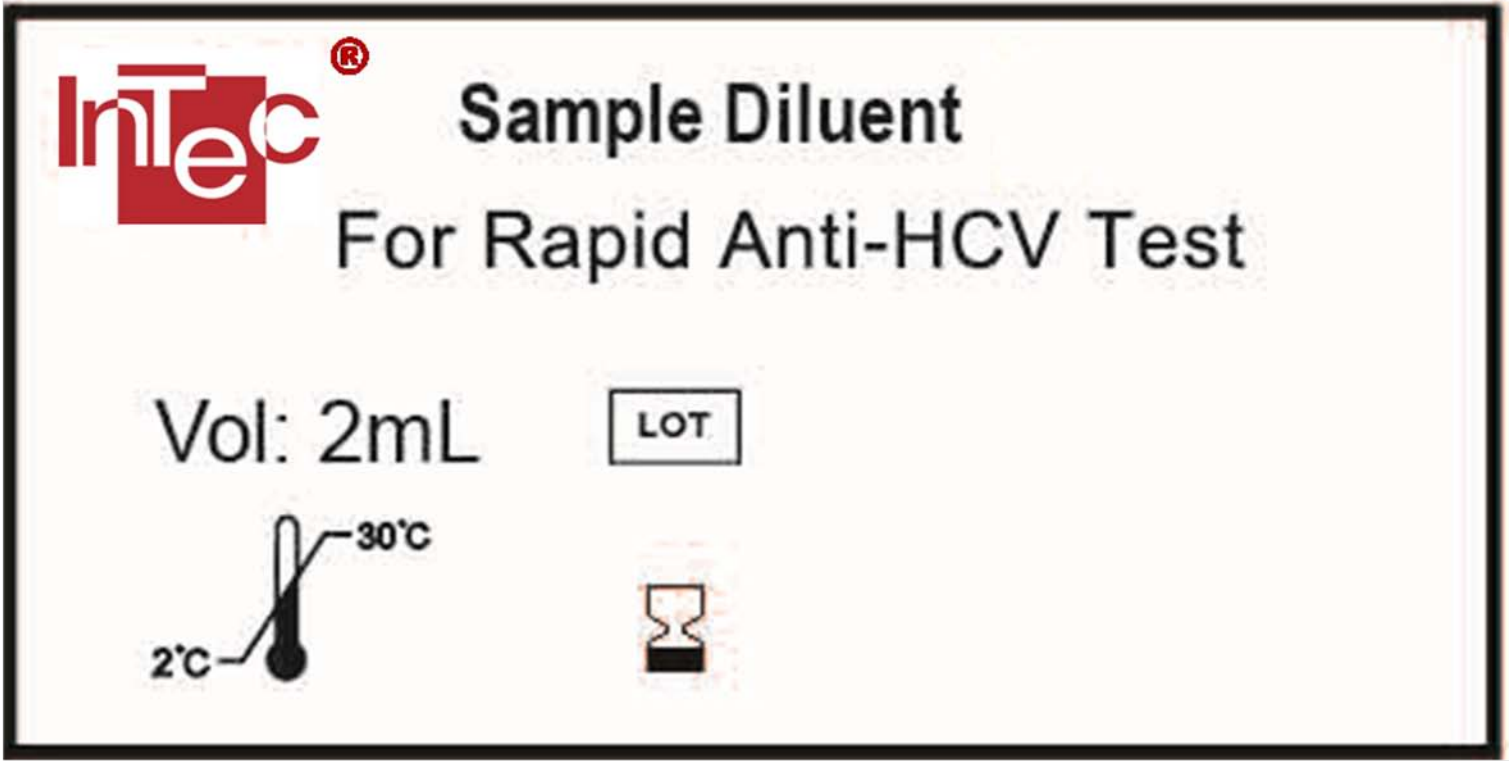
1.4.1 Foil pouch front



1.4.2 Foil pouch back



1.5 Sample diluent label



Rapid Anti-HCV Test

Colloidal Gold (Whole blood/serum/plasma)

Key to symbols used

	CAUTION	30℃ 2℃	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
Σ	CONTAINS SUFFICIENT FOR ‹N› TESTS	STERILE R	STERILIZED USING IRRADIATION

ADVANCED QUALITY™

REF ITPW01152-TC40
ITPW01152-TC25
ITPW01153-TC40

Rapid Anti-HCV 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

Rapid Anti-HCV Test is a colloidal gold enhanced, rapid immunochromatographic assay for qualitative detection of antibodies to hepatitis C virus (HCV) 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 HCV infection.

Summary

Rapid Anti-HCV Test is based on immunochromatography, and is used for virus antibody detection in human whole blood (venous and fingerstick), serum or plasma. This test is simple, convenient and visual and presents the result within 20 minutes.

Test Principle

Recombinant HCV antigen (containing Core, NS2, NS3, NS4, NS5 segments) and mouse anti-human IgG antibody conjugated to colloidal gold are embedded in the sample pad.

If the specimen is positive, the HCV antibody in whole blood, serum or plasma specimen will combine with the colloidal gold conjugated recombinant HCV antigen and generate a complex. As the mixture moves along the test strip, the complex will be captured by the recombinant HCV antigen (containing Core, NS2, NS3, NS4, NS5 segments) immobilized on the membrane, forming a purplish red test band in the test region.

A negative specimen will not form any test band due to the absence of colloidal gold conjugate/HCV antibody complex. Regardless of whether HCV antibodies exist in a specimen, the unbound gold marked protein will bind to the sheep anti-mouse IgG in the control band region and form a purplish red band[1-3].

The assay is only valid when the control band appears.

Storage conditions and stability

Rapid Anti-HCV 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 [4-5]

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

[Warnings]

- This product is for in vitro diagnosis of the infection of HCV 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 recombinant immunoblotting 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 system.

[Precautions]

- Wear gloves during the entire testing process.
- Do not use expired reagents or test cassettes.
- Do not use the accessories if the seal or package is broken.
- Do not use the test cassette if the foil pouch is damaged or the seal is broken.
- Do not use the provided sterile safety lancet 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 test 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 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 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. Used sterile safety lancet should be disposed of in a sharps bin.
- 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.

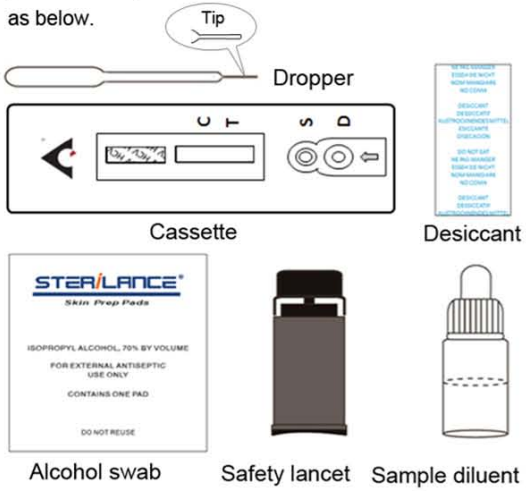
Reagents and Materials Provided

Table 1 Reagent and materials provided

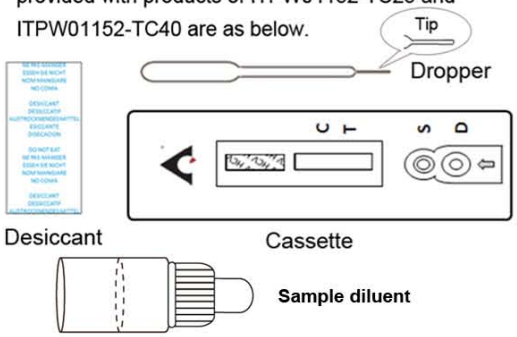
Components	25 tests (ITPW01152-TC25)	40 tests (ITPW01152-TC40)	40 tests (ITPW01153-TC40)
Test cassette	1×25 pieces	1×40 pieces	1×40 pieces
Dropper	1×25 pieces	1×40 pieces	1×40 pieces
Sample diluent	2mL×3 bottles	2mL×4 bottles	2mL×4 bottles
Sterile safety lancet	Not provided	Not provided	1×40 pieces
Alcohol 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 ITPW01153-TC40 are as below.



1b. Unseal the foil pouch. The components provided with products of ITPW01152-TC25 and ITPW01152-TC40 are as below.



2. Wear gloves.

3. Mark the sample ID number.

I. *Fingerstick whole blood*

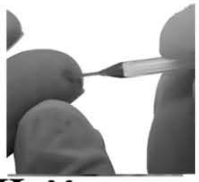
4. Clean the finger with alcohol swab and leave it to dry.

5. Twist the lancet cap for over 90º 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 beneath bulb to collect blood past **tip** of dropper.



9. Add **1 drop** of blood into port S.

10. Add **2 drops** of sample diluent into port D immediately.

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

II. *Venous whole blood*

4. Add **1 drop** of specimen using the provided dropper (gently squeeze and release the part near the bulb for the blood) into port S.

Or

5. Add10μl sample using transfer pipette into port S.

6. Add **2 drops** of sample diluent into port D immediately.

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

III. *Serum/plasma*

4. Add 1 **drop** of specimen using the provided dropper (gently squeeze and release the part near the bulb for the blood) into port S.

Or

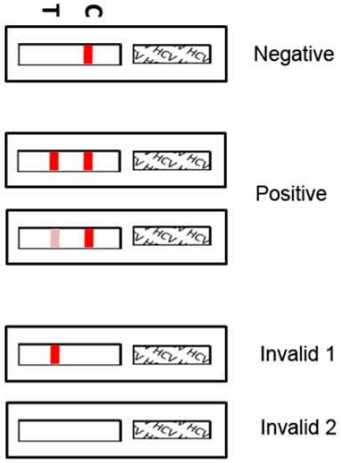
5. Add10μl sample using transfer pipette into port S.

6. Add **2 drops** of sample diluent into port D immediately.

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

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 ITPW01152-TC25 and ITPW01152-TC40)
- Disposable gloves

Specimen collection and storage [6]

Fingerstick whole blood

Rub the target finger to stimulate blood flow. Clean the finger with a 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 cylinder **beneath** bulb of the dropper and touch the blood drop with the dropper tip. Gently release cylinder **beneath** 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 foil 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 platform;
4. Mark the specimen ID number on test cassette;
5. Add 1 drop of the specimen using the provided dropper (or 10μl specimen using transfer pipette) into port "S" of the cassette;
6. Then add 2 drops of diluent into port "D" (diluent port) immediately. Every time before use, the first one to two drops of diluent should be discarded in case of formation of bubble that may influence the test result;
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 the exposure to or the infection with HCV viruses.

Result interpretation

Negative: Purplish red band only appears on control band region indicates a negative result.

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

Invalid 1: A purplish red band appears only at the test band region 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 region nor the test band region of the cassette. Repeat the test. Contact the supplier if the control band remains invisible.

Performance characteristics [7]

The performance of *Rapid Anti-HCV Test* has been evaluated by testing specimens from blood donors, hospitalized patients and commercial seroconversion panels.

Sensitivity

Performance on HCV positive specimens

A study was performed using specimens with confirmed HCV positive status and tested by the *Rapid Anti-HCV Test*.

Table 2 Test results on HCV positive specimens of different specimen types

Population	Specimen Types	Positive by Rapid Anti-HCV Test	Total specimens tested	Sensitivity
Europe	Serum/plasma	210*	212	99.1% 95%CI (96.63-99.89)
	Venous whole blood	100	100	100% 95%CI (96.38-100.00)
	EDTA plasma	100	100	100% 95%CI (96.38-100.00)

***:** The two inconsistent specimens are weak positive, not unequivocally detected by *Rapid Anti-HCV Test*.

Performance on specimens with known HCV genotype

EDTA plasma specimens (n=93) with known HCV-genotype were tested with the *Rapid Anti-HCV test*. All specimens show positive results with clear test bands.

Table 3 Test results on specimens with known HCV genotype.

HCV Genotype	n	Rapid Anti-HCV test results	
		Positive	Negative
1	1	1	0
1a	11	11	0
1b	12	12	0
2a/2c	13	13	0
2b	9	9	0
3a	20	20	0
3b	1	1	0
4c/4d	20	20	0
4h	2	2	0
5a	2	2	0
6	1	1	0
6a	1	1	0
Total	93	93	0

Performance on commercial seroconversion panels[7]

Rapid Anti-HCV Test shows good sensitivity in early infection on available commercial seroconversion panels.

Precision

3 lots of *Rapid Anti-HCV Test* were tested at three different labs by both professional and non-professional operators to analyze the reproducibility and repeatability of the product.

All HCV 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. *Rapid Anti-HCV Test* showed good reproducibility and repeatability in the precision studies.

Specificity

Table 4 Performance on HCV negative specimens

Population	Specimen Type	Rapid Anti-HCV Test			
		Negative	Positive	Total	Specificity
Europe	Venous whole blood	500	0	500	100% 95%CI (99.26-100.00)
	EDTA plasma	996	4	1000	99.6% 95%CI (98.98-99.89)
	Hospitalized patient specimens	199	1	200	99.5% 95%CI (97.25-99.99)
	Pregnant women Specimens	200	0	200	100% 95%CI (98.17-100.00)

Table 5 Test results on potentially cross-reacting specimens

Potential cross-reacting specimens	Rapid Anti-HCV Test		
	Negative	positive	Total
Anti-HBs positive	20	0	20
Anti-HBc positive	20	0	20
Anti-HIV positive	20	0	20
Anti-HTLV positive	20	0	20
Anti-HEV positive	10	0	10
Rheumatoid factor positive	10	0	10
Total	100	0	100

Specimens types

Sensitivity obtained on 100 paired whole blood and plasma specimens of positive patients were 100% with both specimen types. (Table 2)

Specificity obtained from 500 whole blood specimens of blood donors was 100%. (Table 4)

Table 6 Plasma and serum comparison (HCV-negative specimens)

Specimen type	EDTA plasma	Heparin plasma	Citrate plasma	Serum
Tested	25	25	25	25
Negative	25	25	25	25
Positive	0	0	0	0
Specificity	100%	100%	100%	100%

Table 7 Plasma and serum comparison (HCV-positive specimens)

Specimen type	EDTA plasma	Heparin plasma	Citrate plasma	Serum
Tested	25	25	25	25
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/fingerstick whole blood comparison

Specimen (whole blood)	HCV positive specimens		HCV negative specimens	
	Venous	Fingerstick	Venous	Fingerstick
Specimens Tested	25	25	25	25
Negative	0	0	25	25
Positive	25	25	0	0
Concordance rate	100%	100%	100%	100%

According to Table 6, Table 7 and Table 8, *Rapid Anti-HCV Test* can give consistent test results for specimen types serum, plasma, venous whole blood and fingerstick whole blood.

Limitations

- The kit is designed to detect antibodies against HCV in human serum, plasma, and whole blood. Specimens other than specified types may not supply accurate results and the device will not notify this kind of misuses to the user.
- The intensity of 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 conjugate.
- When specimens contain high concentration of antibody to HCV are 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 HCV from individuals, clinical diagnosis of HCV infection should not be made only based on the results of this product.
- A negative result should not exclude the possibility of infection caused by HCV. A negative result can also occur in the following circumstances:
  - Recently acquired HCV infection.
  - Low levels of antibody (e.g., early seroconversion specimens) below the detection limit of the test.
  - HCV 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 genotype of HCV (This product is not validated on genotype 7 specimens).
- 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.
- This 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 of good fluidity without hemolysis can be used with this test;

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