# WHO Prequalification of In Vitro Diagnostics
# PUBLIC ASSESSMENT REPORT

## Product: Rapid Anti-HCV Test
## WHO reference number: PQDx 0371-017-00

Rapid Anti-HCV Test with product codes ITPW01152-TC40, ITPW01152-TC25, ITPW01153-TC40, ITPW01232-TC25, ITPW01232-TC40, ITPW01233-TC25, ITPW01233-TC40, ITPW01253-TC25 and ITPW01253-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 17 May 2019.

## Summary of WHO Prequalification Assessment for the Rapid Anti-HCV Test

| | Date | Outcome |
|---|---|---|
| **Prequalification listing** | 17 May 2019 | listed |
| **Dossier review** | N/A | N/A |
| **Product performance evaluation** | Third 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 amendments and change request reference where applicable. | Date of report amendment |
|---|---|---|
| 2.0 | Updated accessory labels for disposable safety lancets and alcohol swabs for the Rapid Anti-HCV Test to the new regulatory version. | 12 May 2025 |
| 3.0 | Addition of the 6 new specifications of Rapid Anti HCV Test which is under new Reference Nos. ITPW01232-TC25, ITPW01232-TC40, ITPW01233-TC25, ITPW01233-TC40, ITPW01253-TC25 and ITPW01253-TC40. The new narrow cassette with the combination of with and without lancet (lancet/sterile safety lancet) and alcohol swab is introduced in the new specifications. So as the rest of all components, | 12 February 2026 |

| | | |
|---|---|---|
| | production process, quality standard and parameter remain the same. | |
| 4.0 | Update of the labelling references on page 7 of the WHOPAR. | 28 May 2026 |

**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".*

**Test kit contents:**

| Component | 25 Tests (ITPW01152-TC25) | 40 Tests (ITPW01152-TC40) | 40 Tests (ITPW01153-TC40) | 40 Tests (ITPW01253-TC40) | 25 Tests (ITPW01253-TC25 | 25 Tests (ITPW01232-TC25) | 25 Tests (ITPW01233-TC25 | 40 Tests (ITPW01232-TC40) | 40 Tests (ITPW01233-TC40 |
|---|---|---|---|---|---|---|---|---|---|
| Test cassette | 1×25 pieces | 1×40 pieces | 1×40 pieces | 1×40 pieces | 1×25 pieces | 1×25 pieces | 1×25 pieces | 1×40 pieces | 1×40 pieces |
| Dropper | 1×25 pieces | 1×40 pieces | 1×40 pieces | 1×40 pieces | 1×25 pieces | 1×25 pieces | 1×25 pieces | 1×40 pieces | 1×40 pieces |
| Desiccant | 1×25 pieces | 1×40 pieces | 1×40 pieces | 1×40 pieces | 1×25 pieces | 1×25 pieces | 1×25 pieces | 1×40 pieces | 1×40 pieces |
| Sample diluent | 2mL×3 bottles | 2mL×4 bottles | 2mL×4 bottles | 2mL×4 bottles | 2mL×3 bottles | 2mL×3 bottles | 2mL×3 bottles | 2mL×4 bottles | 2mL×4 bottles |
| Sterile Safety lancet | Not provided | Not provided | 1×40 pieces | Not provided | Not provided | Not provided | 1×25 pieces | Not provided | 1×40 pieces |
| Lancet | Not provided | Not provided | Not provided | 1×40 pieces | 1×25 pieces | Not provided | Not provided | Not provided | Not provided |
| Alcohol swab | Not provided | Not provided | 1×40 pieces | 1×40 pieces | 1×25 pieces | Not provided | 1×25 pieces | Not provided | 1×40 pieces |
| Package insert | 1 piece | 1 piece | 1 piece | 1 piece | 1 piece | 1 piece | 1 piece | 1 piece | 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 must be stored between 2 and 30°C.

**Shelf-life upon manufacture[1]:**

24months.

## 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 the 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.

Based on the assessment of the product dossier, Rapid Anti-HCV Test meets the WHO prequalification requirements.

## Manufacturing site inspection

The inspection of the manufacturing site(s) was conducted to assess whether the manufacturer's quality management system (QMS) and manufacturing practices are in alignment with:
(i) applicable international standards, such as ISO 13485 (Medical devices – Quality management systems – Requirements for regulatory purposes);
(ii) the manufacturer's own documented procedures and quality requirements; and

[1] The assigned device shelf-life is based on stability data generated from the date of manufacture. The finished goods shelf-life, calculated from the date of packaging completion, may be shorter depending on the time elapsed between manufacture and final packaging of the device.

(iii) other relevant international standards and guidelines applicable to in vitro diagnostic (IVD) medical devices. The WHO's Public Inspection Reports are accessible at:

https://extranet.who.int/pqweb/vitro-diagnostics/who-public-inspection-reports

## Product performance evaluation

The Rapid Anti-HCV Test (InTec PRODUCTS, Inc) is a rapid, lateral flow immunochromatographic assay for detecting 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 the 20 specimens in the anti-HCV worldwide performance panel were correctly classified.<br>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, the control line on the test device (reagent control) |
| In-use stability of reagents | Sample diluent shall be used within 8 weeks after opening. |

## Labelling review

The labelling submitted for the Rapid Anti-HCV Test was reviewed by WHO staff and external technical experts appointed by WHO. The review evaluated the labelling for clarity and consistency with the information submitted in the product dossier, alignment with international guidance and standards, and suitability for the intended users and settings in WHO Member States, including low- and middle-income countries.

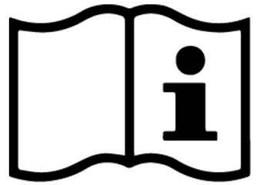
The table below provides traceability of the labelling documents reviewed during the assessment, including document titles, version numbers, approval dates, and control identifiers.

**Controlled Labelling References**

| Document Type | Document Title | Version / Revision | Date Approved | Controlled Document No. |
|---|---|---|---|---|
| Outer box artwork | Carton box HCV -TC25] | 250401 | Apr.2025 | 01.05.02.622 |
| | Carton box HCV -TC40 | 250401 | Apr.2025 | 01.05.02.623 |
| Pouch / Device label | Aluminum foil bag | 220502 | May.2022 | 01.05.13.034 |
| Reagent bottle labels | Diluent | 211102 | Nov.2021 | 01.05.12.021 |
| Accessory labelling | Alcohol swab primary package | NA | NA | NA |
| | Alcohol swab 40Pacs | 240301 | Mar.2024 | 01.04.01.284 |
| | Alcohol swab 25Pacs | 240601 | Jun.2024 | 01.04.00.008 |
| | Lancet for ITPW01153-TC40 | 231101 | Nov.2023 | 01.04.01.277 |
| | Lancet for ITPW01233-TC25 | 250301 | Mar.2025 | 01.04.01.310 |
| | Lancet for ITPW01233-TC40 | 240301 | Mar.2024 | 01.04.01.279 |
| | Lancet for ITPW01253-TC25 | 240601 | Jun.2024 | 01.04.00.010 |
| | Lancet for ITPW01253-TC40 | 240601 | Jun.2024 | 01.04.00.011 |
| Instructions for Use (IFU) | IFU for ITPW01232&01233 | 260101 | Jan.2026 | 01.05.14.239 |
| | IFU for ITPW01253 | 260101 | Jan.2026 | 01.05.14.240- |
| | IFU for ITPW01152&01153 | 250406 | Apr.2025 | 01.05.14.075 |

**Labels**

# Sample Diluent
# For Rapid Anti-HCV Test


Vol:2mL/bottle


Storage： 2-30℃

# Alcohol Swabs

Produce Code：06-023060
Specifications of Blade：30mm × 60mm
Qty: 25Pcs/Bag

Manufacturer:
SteriLance Medical ( Suzhou ) Inc .
No.168 PuTuoShan Road, New District,
215153 Suzhou,Jiangsu, P.R.China

6 945630 100000

REF 06-023060

LOT XXXXX

YYYY-MM-DD

YYYY-MM-DD

Intended use： It's used for skin disinfection before blood sampling, injection and infusion.

Instructions for Use：
1. Open the package and take out the alcohol swab;
2. Use the alcohol swab to wipe the skin;
3. After the alcohol on the surface is dried, the disinfection is completed;
4. Discard the used alcohol swab in the special container.

Contraindications：
1. Do not use if there is skin infection or skin damage on the wiping part.
2. It should be used with caution or follow the doctor's advice for the user allergic to alcohol.

Caution：
• This product is not suitable for trauma or burns. Stop the use and consult your doctor if you have symptoms of redness, allergies, swelling, pain or inflammation.
• Do not use the product if the package of alcohol swab is damaged.
• Alcohol swab is for external use only, not for eyes or mucous membrane. Please consult your doctor if it touches the wound.
• Do not use if there is skin infection or skin damage on the wiping part.
• The alcohol swab is for single use and shall be kept away from naked fire.
• Keep the alcohol swab away from children.
• Do not use beyond the use-by date.

Symbolic interpretation:

Do not re-use | Caution | Catalogue number | Do not use if package is damaged | Manufacturer

Batch code | Date of manufacture | Use-by date

# Alcohol Swabs

Produce Code：06-023060
Specifications of Blade：30mm × 60mm
Qty: 40Pcs/Bag

Manufacturer:
SteriLance Medical ( Suzhou ) Inc .
No.168 PuTuoShan Road, New District,
215153 Suzhou,Jiangsu, P.R.China

6 945630 100000

REF 06-023060

LOT XXXXX

YYYY-MM-DD

YYYY-MM-DD

Intended use： It's used for skin disinfection before blood sampling, injection and infusion.

Instructions for Use：
1. Open the package and take out the alcohol swab;
2. Use the alcohol swab to wipe the skin;
3. After the alcohol on the surface is dried, the disinfection is completed;
4. Discard the used alcohol swab in the special container.

Contraindications：
1. Do not use if there is skin infection or skin damage on the wiping part.
2. It should be used with caution or follow the doctor's advice for the user allergic to alcohol.

Caution：
• This product is not suitable for trauma or burns. Stop the use and consult your doctor if you have symptoms of redness, allergies, swelling, pain or inflammation.
• Do not use the product if the package of alcohol swab is damaged.
• Alcohol swab is for external use only, not for eyes or mucous membrane. Please consult your doctor if it touches the wound.
• Do not use if there is skin infection or skin damage on the wiping part.
• The alcohol swab is for single use and shall be kept away from naked fire.
• Keep the alcohol swab away from children.
• Do not use beyond the use-by date.

Symbolic interpretation:

Do not re-use | Caution | Catalogue number | Do not use if package is damaged | Manufacturer

Batch code | Date of manufacture | Use-by date

STERILANCE®

Skin Prep Pads

ISOPROPYL ALCOHOL, 70% BY VOLUME

FOR EXTERNAL ANTISEPTIC
USE ONLY

CONTAINS ONE PAD

DO NOT REUSE

## 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.

STERILANCE™ Press 2

# Safety Lancets

Reorder No.: 05-062122
Specification: 21G 2.2mm
Qty: 20Pcs/Bag

Manufactured for InTec PRODUCTS, INC.

EC REP

European Authorized Representative
Emergo Europe B.V.
Westervoortsedijk 60,
6827 AT Arnhem, The Netherlands

Manufacturer:
SteriLance Medical ( Suzhou ) Inc .
No.168 PuTuoShan Road, New District,
215153 Suzhou, Jiangsu,
PEOPLE'S REPUBLIC OF CHINA

(01)16945630119955
(11)
(17)
(10)

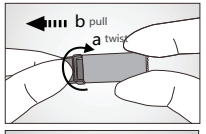
REF 05-062122

LOT XXXXX

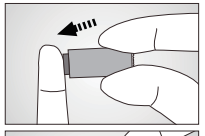
YYYY-MM-DD

YYYY-MM-DD

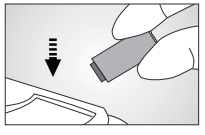
Instructions for Use :




1.Carefully twist off the protective cap until it is separated from the device.



2. Place the lancet firmly against the puncture site to activate. Do not remove the device until an audible click is heard.



3. Discard the used lancet into a suitable sharps container.

Intended use :
The safety lancet is used for capillary blood collection.
Contraindications : Unknown.

Caution :
1.Do not use if lancet cap has been previously removed from lancet.
2.Check the use-by date on the packaging, and do not use the lancet beyond the use-by date.
3.The safety lancet is for disposable use and do not reuse the lancet.
4.Discard the used lancet into a suitable sharps container.

Symbolic interpretation:

STERILE R — Sterilized using irradiation
Do not re-use
EC REP — European Authorized Representative
Caution
MD — Medical Device
Manufacturer
LOT — Batch code
Date of manufacture
Use-by date
Consult instructions for use
CE 0123 — Notified Body
Safety Lancets — Disposable safety lancets
REF — Catalogue number

Revised date: June 19, 2023 (Version 03)

Safety Lancets

Reorder No.:W147

Specification:21G2.2mm

Qty: 25Pcs/Bag

Manufactured for InTec PRODUCTS, INC.

EC REP Llins Service & Consulting GmbH
Heinigstrasse 26, 67059 Ludwigshafen, Germany

Suzhou Kyuan Medical Apparatus Co., Ltd.
Dangdong Road and Edong Road,Beiqiao Town,
Suzhou City, 215144, Jiangsu, P.R.China

(01)06971517660381
(11)
(17)
(10)

REF

LOT

Instructions for Use:

1. Carefully twist off the protective cap until it is separated from the device.

2. Place the lancet firmly against the puncture site to activate. Do not remove the device until an audible click is heard.

3. Discard the used lancet into a suitable sharps container.

Intended use:
The product is used to obtain capillary blood samples from fingertip. The device contains a sharp injury protection feature.
Contraindications: Not Clear
Caution:
1. Do not use if lancet cap has been removed.
2. The product is disposable, the used product is treated as medical waste to be destroyed.
3. Safety lancets can be used only once to prevent cross infection.
4. This product should be stored in a well-ventilated room without corrosive gas and away from fire.
5. The shelf life of safety lancets is 5 years.

Symbolic intertaion:

STERILE R — Sterilized using Irradiation
Do not re-use
EC REP — European Authorized representative
Caution
MD — Medical device
Manufacturer
LOT — Batch code
Date of manufacture
Use-by date
Consult instructions for use
CE 0197 — Notified Body
Safety Lancets — Disposable safety lancets
REF — Catalogue number
Single sterile barrier system

# Disposable safety lancet label- Suzhou Kyuan Medical Apparatus Co., Ltd.

Safety Lancets

Reorder No.:

Specification:

Qty: 20Pcs/Bag

Manufactured for InTec PRODUCTS, INC.

EC REP Llins Service & Consulting GmbH
Heinigstrasse 26, 67059 Ludwigshafen, Germany

Suzhou Kyuan Medical Apparatus Co., Ltd.
Dangdong Road and Edong Road,Beiqiao Town,
Suzhou City, 215144, Jiangsu, P.R.China

(01) 06971517660459
(11)
(17)
(10)

REF

LOT

Instructions for Use:

1. Carefully twist off the protective cap until it is separated from the device.

2. Place the lancet firmly against the puncture site to activate. Do not remove the device until an audible click is heard.

3. Discard the used lancet into a suitable sharps container.

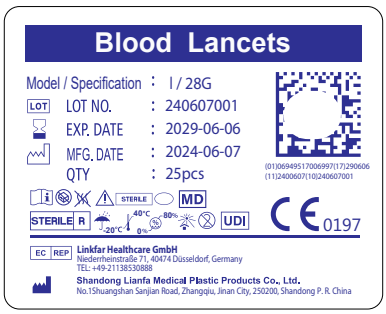
Intended use:
The product is used to obtain capillary blood samples from fingertip. The device contains a sharp injury protection feature.
Contraindications: Not Clear
Caution:
1. Do not use if lancet cap has been removed.
2. The product is disposable and the used product is treated as medical waste to be destroyed.
3. Safety lancets can be used only once to prevent cross infection.
4. This product should be stored in a well-ventilated room without corrosive gas and away from fire.
5. The shelf life of safety lancets is 5 years.

Symbolic intertaion:

STERILE R — Sterilized using irradiation
Do not re-use
EC REP — European Authorized representative
Caution
MD — Medical device
Manufacturer
LOT — Batch code
Date of manufacture
Use-by date
Consult instructions for use
CE 0197 — Notified Body
Safety Lancets — Disposable safety lancets
REF — Catalogue number
Single sterile barrier system

PANTONE Reflex Blue C

Size:50*40mm



PANTONE Reflex Blue C

Size:50*40mm

# Blood Lancets

Model / Specification : I / 28G

LOT LOT NO. : 240607002

EXP. DATE : 2029-06-06

MFG. DATE : 2024-06-07

QTY : 40pcs

(01)06949517007000(17)290606
(11)240607(10)240607002

STERILE MD

STERILE R -20°C 40°C 0% 80% UDI

CE 0197

EC REP **Linkfar Healthcare GmbH**
Niederrheinstraße 71, 40474 Düsseldorf, Germany
TEL: +49-21138530888

**Shandong Lianfa Medical Plastic Products Co., Ltd.**
No.15huangshan Sanjian Road, Zhangqiu, Jinan City, 250200, Shandong P. R. China

01.05.13.034-220502

Rapid Anti-HCV Test **HCV**

Colloidal Gold (Whole Blood/Serum/Plasma)

ADVANCED QUALITY
IN MEDICAL DIAGNOSTICS

# Rapid Anti-HCV Test

REF

LOT

**Contents**

**1 Test**

**1 Dropper**

**1 Desiccant**

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

IVD

ADVANCED QUALITY
IN MEDICAL DIAGNOSTICS

# HCV

Colloidal Gold (Whole Blood/Serum/Plasma)

IVD

InTec PRODUCTS. INC.

HCV

ADVANCED QUALITY
IN MEDICAL DIAGNOSTICS

HCV

ADVANCED QUALITY
IN MEDICAL DIAGNOSTICS

HCV

ADVANCED QUALITY
IN MEDICAL DIAGNOSTICS

HCV

Rapid Anti-HCV Test

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

01.05.02.622-250401

ADVANCED QUALITY
IN MEDICAL DIAGNOSTICS

HCV

Colloidal Gold (Whole Blood/Serum/Plasma)

IVD

InTec PRODUCTS. INC

HCV

HCV

HCV

InTec PRODUCTS. INC.

InTec PRODUCTS. INC.
Tel: +86-592-6087188
Website: www.intecsz.com
Email: intecproducts@outlook.com

Rapid Anti-HCV Test

01.05.02.023-250401

**Instructions for Use[2]**

[2] 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.

01.05.14.075-250406

# Rapid Anti-HCV Test

Colloidal Gold (Whole blood/serum/plasma)

## Key to symbols used

| | | | |
|---|---|---|---|
|  | CAUTION |  | TEMPERATURE LIMIT |
|  | 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

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.

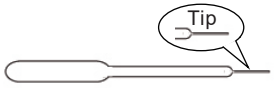
## Reagents and Materials Provided

Table 1 Reagent and materials provided

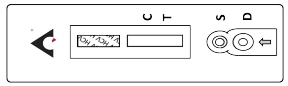
| Components | 25 tests (ITPW01152-TC25) | 40 tests (ITPW01152-TC40) | 40 tests (ITPW01153-TC40) |
|---|---|---|---|
| Test cassette | 1×25 pieces | 1×40 pieces | 1×40 pieces |
| Dropper | 1×25 pieces | 1×40 pieces | 1×40 pieces |
| Desiccant | 1×25 pieces | 1×40 pieces | 1×40 pieces |
| Sample diluent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



Dropper



Cassette

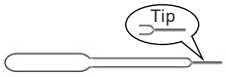

Desiccant

Alcohol swab

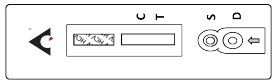

Safety lancet


Sample diluent

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



Dropper

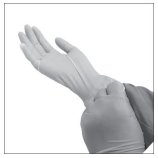


Cassette


Desiccant


Sample diluent

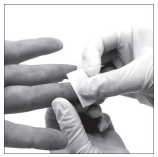
***2.*** Wear gloves.



***3.*** Mark the sample ID number.

## *I. Fingerstick whole blood*

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



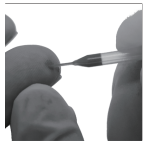
***5.*** Twist the lancet cap for over 90° and remove it.

***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 beneath bulb to collect blood past tip of dropper.



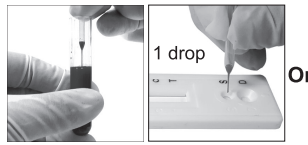
***9.*** Add **1 drop** of blood into port S.


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

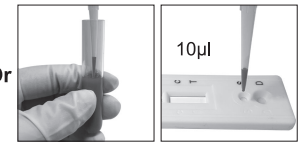

***11.*** Wait and interpret the result between 15-20 minutes.


## *II. Venous whole blood*

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




***4b.*** Add 10µl sample using transfer pipette into port S.

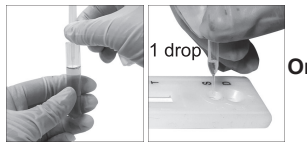



***5.*** Add **2 drops** of sample diluent into port D immediately.

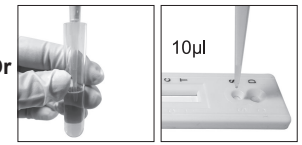

***6.*** Wait and interpret the result between 15-20 minutes.


## *III. Serum/plasma*

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




***4b.*** Add 10µl sample using transfer pipette into port S.

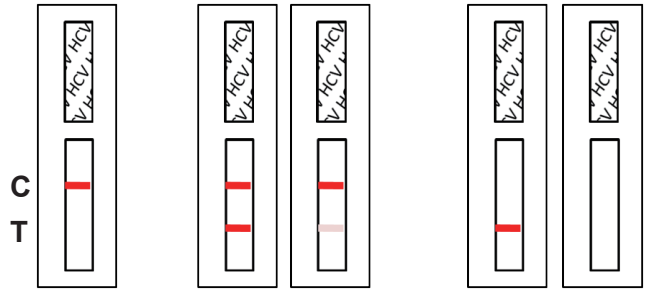



***5.*** Add **2 drops** of sample diluent into port D immediately.


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


## *Result interpretation*

See package insert for details.



Negative Positive Invalid 1 Invalid 2

**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 |
|---|---|---|---|---|
| | Serum/plasma | 210* | 212 | 99.1%<br>95%CI (96.63-99.89) |
| Europe | Venous whole blood | 100 | 100 | 100%<br>95%CI (96.38-100.00) |
| | EDTA plasma | 100 | 100 | 100%<br>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 Venous | Fingerstick | HCV negative specimens 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;



**References**

1. Ju Ying, Cao Yuan-yin. Colloidal Gold Immunochromatography Rapid Diagnostic Technolog. Progress in Modern Biomedicine. 2009 Vol.9 No.11.
2. Qing-Lei Zeng, Guo-Hua Feng, Ji-Yuan Zhang, Yan Chen, Bin Yang, Hui-Huang Huang, Xue-Xiu Zhang,Zheng Zhang, Fu-Sheng Wang et al. Risk factors for liver-related mortality in chronic hepatitis C patients:A deceased case-living control study. World J Gastroenterol 2014 May 14; 20(18): 5519-5526.
3. Esteban JI, Gonzalez A, Hernandez JM et al. Evaluation of antibodies to hepatitis C virus in a study of transfusion-associated hepatitis. N Engl J Med 1990; 323:1107-12.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, Sanquin Diagnostic Services. July 2015.
7. Evaluation report, Paul-Ehrlich-Institut (PEI-IVD). May 2015.

REF ITPW01232-TC40
ITPW01232-TC25
ITPW01233-TC40
ITPW01233-TC25
01.05.14.239-260101

# 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°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[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°C 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.
- 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

| Components | 25 Tests (ITPW01232-TC25) | 25 Tests (ITPW01233-TC25) | 40 Tests (ITPW01232-TC40) | 40 Tests (ITPW01233-TC40) |
|---|---|---|---|---|
| Test cassette | 1×25 pieces | 1×25 pieces | 1×40 pieces | 1×40 pieces |
| Dropper | 1×25 pieces | 1×25 pieces | 1×40 pieces | 1×40 pieces |
| Desiccant | 1×25 pieces | 1×25 pieces | 1×40 pieces | 1×40 pieces |
| Sample diluent | 2mL×3 bottles | 2mL×3 bottles | 2mL×4 bottles | 2mL×4 bottles |
| Sterile safety lancet | Not provided | 1×25 pieces | Not provided | 1×40 pieces |
| Alcohol swab | Not provided | 1×25 pieces | Not provided | 1×40 pieces |
| Package insert | 1 piece | 1 piece | 1 piece | 1 piece |

## 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 bin and sharps bin
- Sterile safety lancet and alcohol swab (product code ITPW01232-TC25 and ITPW01232-TC40)
- Disposable gloves

## Specimen collection and storage[6]

### *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 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°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 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.

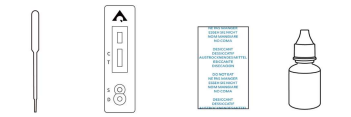
### Notes:

- Serum or plasma specimens shall be stored at 2-8°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 shall 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.

## Preparation

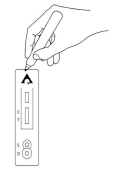
***1a.*** Unseal the foil pouches. The components provided with products of ITPW01233-TC25 and ITPW01233-TC40 are as below.


***1b.*** Unseal the foil pouches. The components provided with products of ITPW01232-TC25 and ITPW01232-TC40 are as below.




***2.*** Wear gloves.

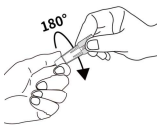
***3.*** Mark the sample ID number.



***I .Fingerstick whole blood***

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

***5.*** Twist the lancet cap more than 180° and removeit.

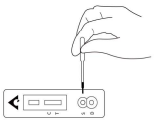



***6.*** Place the lancet firmly on side of the finger (avoid callus) to trigger it.

***7.*** Wipe away the first drop of blood. Massage finger to create a whole 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**.



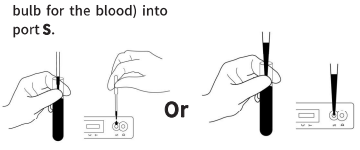
***10.*** Add **2 drops** of sample diluent into port **D** immediately.

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

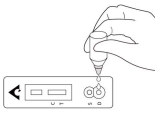

***II . Venous whole blood/Serum/Plasma***

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

***4b.*** Add **10 µL** sample using transfer pipette into port **S.**




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



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


## Test procedure

1. Do not open the foil pouch until ready to perform a test. Use the test immediately after opening the foil pouch.
2. Equilibrate all reagents and specimens to room temperature (10-30°C) 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.

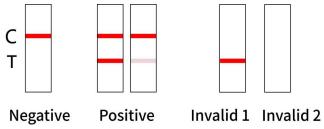
6. Then add 2 drops of diluent into port "D" (diluent port) immediately. Every time before use, the first one to two drops of diluent should be discarded in case of formation of bubble that may influence the test result.
7. Wait and interpret the result between 15-20 minutes.

## ⚠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

See package insert for details




**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%<br>95%CI (96.63%-99.89%) |
| | Venous whole blood | 100 | 100 | 100%<br>95%CI (96.38%-100.00%) |
| | EDTA plasma | 100 | 100 | 100%<br>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

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

## References

1. Ju Ying, Cao Yuan-yin. Colloidal Gold Immunochromatography Rapid Diagnostic Technolog. Progress in Modern Biomedicine. 2009 Vol.9 No.11.
2. Qing-Lei Zeng, Guo-Hua Feng, Ji-Yuan Zhang, Yan Chen, Bin Yang, Hui-Huang Huang, Xue-Xiu Zhang, Zheng Zhang, Fu-Sheng Wang et al. Risk factors for liver-related mortality in chronic hepatitis C patients: A case-living control study. World J Gastroenterol 2014 May 14; 20(18): 5519-5526.
3. Esteban JI, Gonzalez A, Hernandez JM et al. Evaluation of antibodies to hepatitis C virus in a study of transfusion-associated hepatitis. N Engl J Med 1990; 323:1107-12. 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, Sanquin Diagnostic Services. July 2015.
7. Evaluation report, Paul-Ehrlich-Institut (PEI-IVD). May 2015.

## Symbols

| | | | | | |
|---|---|---|---|---|---|
| | Caution | | Keep dry | | Do not re-use |
| | Keep away from sunlight | | Temperature limit | | Contain sufficient for <n> test |
| | Manufacturer | IVD | In vitro diagnostic medical device | | Use-by date |
| LOT | Batch code | REF | Catalogue number | | Do not use if package is damaged and consult instructions for use |
| | Consult instructions for use | STERILE R | Sterilized using irradiation | | |

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Email: intecproducts@asintec.com

REF ITPW01253-TC40
ITPW01253-TC25
01.05.14.240-260101

# 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 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°C 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.
- 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

| Components | 25 Tests (ITPW01253-TC25) | 40 Tests (ITPW01253-TC40) |
|---|---|---|
| Test cassette | 1×25 pieces | 1×40 pieces |
| Dropper | 1×25 pieces | 1×40 pieces |
| Desiccant | 1×25 pieces | 1×40 pieces |
| Sample diluent | 2mL×3 bottles | 2mL×4 bottles |
| Lancet | 1×25 pieces | 1×40 pieces |
| Alcohol swab | 1×25 pieces | 1×40 pieces |
| Package insert | 1 piece | 1 piece |

## 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 bin and sharps bin
- Disposable gloves

## Specimen collection and storage[6]

### *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 lancet (for the provided lancet: a. Twist the lancet cap clockwise, more than 180° and remove it, see Figure I.5 for details; b. Place the lancet firmly on side of finger (avoid callus) and push, 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°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 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*

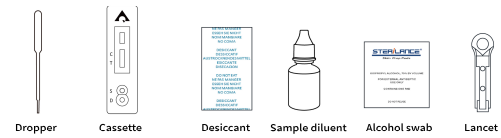
Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA, heparin sodium or sodium citrate) according to standard venous blood sampling process. Gently invert the collection tube for several times and leave to settle for 30 minutes for blood coagulation, then centrifuge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

### Notes:

- Serum or plasma specimens shall be stored at 2-8°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 shall 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.

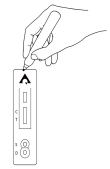
## Preparation

***1a.*** Open the foil pouch and look for the following components as below:



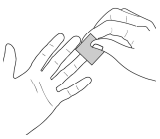

***2.*** Wear gloves.

***3.*** Mark the sample ID number.

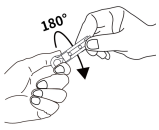


***I . Fingerstick whole blood***

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

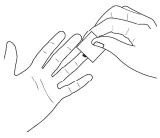


***5.*** Twist the lancet cap more than 180° and remove it.



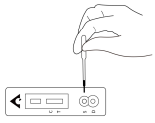

***6.*** Place the lancet firmly on side of the finger (avoid callus) and push.

***7.*** Wipe away the first drop of blood. Massage finger to create a whole drop of blood.



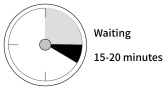
***8.*** Use dropper to collect specimen. Gently squeeze and release beneath bulb to collect blood past tip of dropper.

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



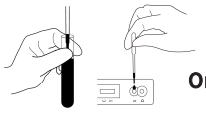
***10.*** Add **2 drops** of sample diluent into port **D** immediately.

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

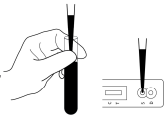



***II . Venous whole blood/Serum/Plasma***

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



***4b.*** Add **10μL** sample using transfer pipette into port **S.**




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

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


## Test procedure

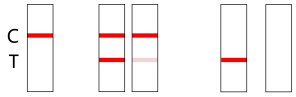
1. Do not open the foil pouch until ready to perform a test. Use the test immediately after opening the foil pouch.
2. Equilibrate all reagents and specimens to room temperature (10-30°C) before use.
3. Unseal the foil pouch and put the cassette on a clean, dry and level platform.
4. Mark the specimen 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

See package insert for details




Negative Positive Invalid 1 Invalid 2

**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%<br>95%CI (96.63%-99.89%) |
| | Venous whole blood | 100 | 100 | 100%<br>95%CI (96.38%-100.00%) |
| | EDTA plasma | 100 | 100 | 100%<br>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 Positive | Rapid Anti-HCV Test 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%<br>95%CI (99.26%-100.00%) |
| | EDTA plasma | 996 | 4 | 1000 | 99.6%<br>95%CI ( 98.98%-99.89%) |
| | Hospitalized patient specimens | 199 | 1 | 200 | 99.5%<br>95%CI( 97.25%-99.99%) |
| | Pregnant women Specimens | 200 | 0 | 200 | 100%<br>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 Venous | HCV positive specimens Fingerstick | HCV negative specimens Venous | HCV negative specimens 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.

## References

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## Symbols

| | | | | | |
|---|---|---|---|---|---|
|  | Caution |  | Keep dry |  | Do not re-use |
|  | Keep away from sunlight |  | Temperature limit |  | Contain sufficient for <n> test |
|  | Manufacturer | IVD | In vitro diagnostic medical device |  | Use-by date |
| LOT | Batch code | REF | Catalogue number |  | Do not use if package is damaged and consult instructions for use |
|  | Consult instructions for use | STERILE R | Sterilized using irradiation | | |

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