DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 060578 0021 Rev. 00

Holder of Certificate: **InTec PRODUCTS, INC.**
332 Xinguang Road
Xinyang Industrial Area, Haicang
361022 Xiamen, Fujian
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
InTec PRODUCTS, INC.
332 Xinguang Road, Xinyang Industrial Area, Haicang, 361022
Xiamen, Fujian, PEOPLE'S REPUBLIC OF CHINA

InTec PRODUCTS, INC.
308-8 Wengjiao Road, Xinyang Industrial Area, Haicang, 361022
Xiamen, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Kits for Immunochemistry, Infectious Diseases, Clinical Chemistry, Haemostasis (Coagulation) and Related Instruments**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1829614

Valid from: 2018-07-31
Valid until: 2021-07-30

Date, 2018-07-16

Stefan Preiß

IDNO 1002600053289
«MEDEFERENT GRUP»

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DECLARATION OF CONFORMITY

Manufacturer	**InTec PRODUCTS, INC.** 332 Xinguang Road, Xinyang Industrial Area, Haicang, 361022, Xiamen, Fujian, P. R. China
Authorized Representative	**Qarad b.v.b.a** Cipalstraat 3, B-2440 Geel, Belgium
Product Name	Rapid Anti-HCV Test
Product Code	ITPW01152-TC25, ITPW01152-TC40, ITPW01153-TC40
CE Certificate	V10605780020 Rev.02 (valid until 2024-05-26)
Classification:	List A
Notified Body:	(NB 0123) TÜV SÜD Product Service GmbH TÜV SÜD Gruppe - Zertifizierstelle Ridlerstr. 65 – 80339 München Germany

Standards applied:

No.	Reference	Title of Harmonized Standard
01	EN ISO 13485: 2016	Medical device-Quality management systems-Requirements for regulatory purposes
02	EN ISO 14971:2012	Medical device-Application of risk management to medical devices
03	EN ISO 15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
04	EN 13612:2002	Performance evaluation of *in vitro* diagnostic medical devices
05	EN ISO 18113-1:2011	Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
06	EN ISO 18113-2:2011	Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
07	EN ISO 23640: 2015	In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
08	EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
09	2009/886/EC	Common Technical Specifications for In Vitro Diagnostic Medical Devices
10	EN 62366:2008	Medical devices-Application of usability engineering to medical devices
11	REGULATION (EC) No 1272/2008	REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
12*	EN ISO 11137-1:2015	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
13*	EN ISO 11137-2:2015	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose

* Only applicable to accessory sterile disposable safety lancets; only ITPW01153-TC40 contains sterile disposable safety lancets.

InTec PRODUCTS, INC.

Date: February 25, 2021
Lumin Jiao (Authorized Signatory)
General Manager
InTec PRODUCTS, INC. Place: Xiamen, China

Add: 332 Xinguang Road, Xinyang Industry Area, Haicang
Xiamen

Tel: +86 592 6807188
Fax: +86 592 6519161

InTec PRODUCTS

CERTIFICATE OF ANALYSIS

Component	RAPID ANTI-HCV TEST CARD
Format/Label	TC 40
Catalog Number	ITPW01153-TC40
Lot Number	GJ20080634
Date of manufacture	Aug, 2020
Expiration Date	Aug, 2022
Storage	2-30℃in Dry Condition
Physical Appearance	Conformed
Lot Size	24,600

QUALITY CONTROL DATA SHEET

Function Test	**Specification**	**Result for this Lot** (Pass/Fail)
Anti-HCV Negative	invisible line on TL area within 15 minutes	Pass
Anti-HCV Weak Positive	visible line on TL area within 5 minutes	Pass
Anti-HCV Medium Positive	visible line on TL area within 3 minutes	Pass
Anti-HCV Strong Positive	visible line on TL area within 1 minutes	Pass
Control Line	visible line on CL area within 2 minutes	Pass

Test Results: Passed

Date Released: Sep,01,2020

Operated by Qi Huang, Yan

INTEC PRODUCTS, INC (XIAMEN)

Reviewed by Jinfeng, Zhang

IDNO 1002600053289 «MEDEFERENT GRUP» S.R.L.

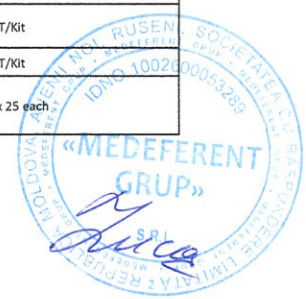
World Health Organization

WHO list of prequalified in vitro diagnostic products

RoW: Rest of the world. Regulatory version applied to products not approved by stringent/mature NRAs or not regulated

Last update: 13 October 2020

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
2019	HBsAg RDT	*Determine HBsAg 2	7D2942; 7D2943; 7D2943 SET	CE-mark	Alere Medical Co. Ltd	357 Matsuhidai, Matsudo-shi, 270-2214, Chiba-ken, Japan	20 T/kit 100 T/kit 100 T/kit
2019	HCV EIA	ARCHITECT HCV Ag assay	6L47-29; 6L47-11; 6L47-02; and 8C89-01	CE-mark	Denka Seiken Co., LTD, Kagamida Factory	Street 1359-1, Kagamida, Kigoshi, Gosen-shi, Niigata, Japan	100 T/kit
2019	HIV RDT for self-testing	*Mylan HIV Self Test	ARST001-03	RoW	Atomo Diagnostics Pvty. Ltd	**Site 1:** Atomo Diagnostics Pty Ltd atLevel 2, 701-703 Parramatta Road, Leichardt 2040 NSW, Australia **Site 2:** Lateral Flow Laboratories (LFL) at Unit 1 & 2, Greenwich Place, Capricorn Crescent, Capricorn Technology Park, Muizenberg,7945, South Africa	1 T/kit
2019	HIV/Syp RDT	*First Response HIV1+2/Syphilis Combo Card Test	I20FRC25; I20FRC30; I20FRC50; I20FRC60; I20FRC100	RoW	Premier Medical Corporation Private Limited	Sarigam, Gujarat, India	25 T/kit 30 T/kit 50 T/kit 60 T/kit 100 T/kit
2019	HIV RDT	*ONE STEP Anti-HIV (1&2) Test	ITPW02152-TC40; ITPW02152-TC25; ITPW02153-TC40 ITPW02153-TC40SA	RoW	InTec PRODUCTS, INC	308, Wengjiao Rd, Xinyang IND. AREA, Haicang, Xiamen, 361022, China	40 T/kit 25 T/kit 40 T/kit 40 T/kit
2019	HCV RDT	Rapid Anti-HCV Test	ITPW01152-TC40; ITPW01152-TC25; ITPW01153-TC40	RoW	InTec PRODUCTS, INC	308, Wengjiao Rd, Xinyang IND. AREA, Haicang, Xiamen, 361022, China	40 T/kit 25 T/kit 40 T/kit
2019	Malaria RDT	AdvDx Malaria Pf Rapid Malaria Ag Detection Test	00-DKM-RK-MALADX-004-025	RoW	Advy Chemical Pvt Ltd.,	Plot No.A-334,336,338 & A-337 & 339 Road no. 25 & 26, Wagle industial Estate Thane 400 604 India	25 T/kit
2019	Malaria RDT	*NxTek Eliminate Malaria Pf	05FK140	CE-mark	Abbott Diagnostics Korea Inc	**site 1:** 46, Hagal-ro 15 beongil, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea **site 2:** 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of	25T/Kit
			05FK141				25T/Kit
			05FK142				1T/kit x 25 each



Advanced Quality

01.05.14.075—191103
Release date: 20191111

Rapid Anti-HCV Test

Colloidal Gold (Whole blood/serum/plasma)

Key to symbols used

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

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

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**" well 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.

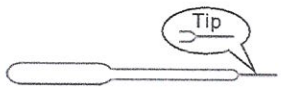
Reagents and Materials Provided

Table 1 Reagent and materials provided

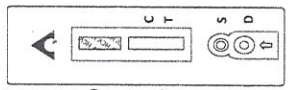
Components	25 tests (ITPW01152-TC25)	40 tests (ITPW01152-TC40)	40 tests (ITPW01153-TC40)
Test cassette	1×25 pieces	1×40 pieces	1×40 pieces
Dropper	1×25 pieces	1×40 pieces	1×40 pieces
Desiccant	1×25 pieces	1×40 pieces	1×40 pieces
Sample diluent	2mL×3 bottles	2mL×4 bottles	2mL×4 bottles
Sterile safety lancet	Not provided	Not provided	2×20 pieces
Alcohol swab	Not provided	Not provided	1×40 pieces
Package insert	1×1 piece	1×1 piece	1×1 piece

Preparation

1a. Unseal the foil pouches. The components provided with products of ITPW01153-TC40 are as below.



Dropper

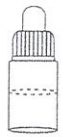


Cassette

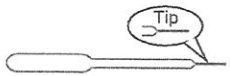

Desiccant

Alcohol swab

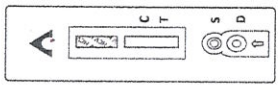

Safety lancet


Sample diluent

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

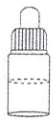


Dropper



Cassette


Desiccant


Sample diluent

2. Wear gloves.

3. Mark the sample ID number.

I. Fingerstick whole blood

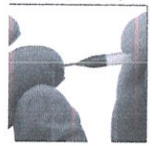
4. Clean the finger with alcohol swab and leave it to dry.

5. Twist the lancet cap for over 180° and remove it.

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

7. Gently massage around 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 **"S"** well.

10. Add **2 drops** of sample diluent into **"S"** well immediately.

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

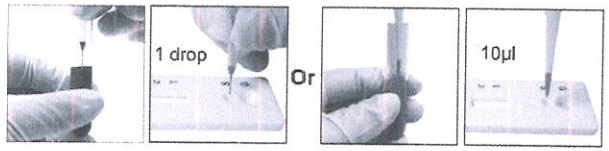
II. Venous whole blood

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

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

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

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



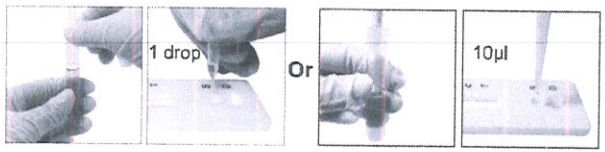
III. Serum/plasma

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

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

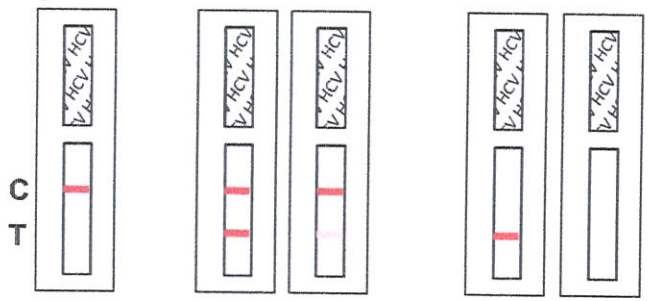
5. Add **2 drops** of sample diluent into **"D"** well immediately.

6. 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 **"S"** well of the cassette;
6. Then add 2 drops of diluent into **"D"** well (diluent well) 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 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;

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