REF ITP01152-TC40
ITP01152-TC25
ITP01153-TC40
ITP01153-TC10

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EC REP **Qarad b.v.b.a**
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CE 0123

ADVANCED QUALITY™

01.05.14.069—170703
Release date：20170717

Rapid Anti-HCV Test

Diagnostic Kit for Antibody to Hepatitis C Virus (Colloidal Gold)
(Whole blood/Serum/Plasma)

Key to symbols used:

REF Catalogue Number

IVD In Vitro Diagnostic Medical Device

Manufacturer

CE Mark

2℃ 30℃ Store at 2-30℃

Use-by date

Do Not Reuse

CAUTION

Consult Instructions For Use

Σ 10 Contains sufficient material for 10 tests

Σ 25 Contains Sufficient material for 25 tests

Σ 40 Contains Sufficient material for 40 tests

ADVANCED QUALITY™

ITP01152-TC40
ITP01152-TC25
ITP01153-TC40
ITP01153-TC10

Rapid Anti-HCV Test

Diagnostic Kit for Antibody to Hepatitis C Virus (Colloidal Gold)
(Whole blood/Serum/Plasma)

For in vitro diagnostic use only
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 the qualitative detection of antibodies to hepatitis C virus (HCV) in human whole blood, serum or plasma. This test is a rapid test used as an aid for diagnosis and all positive results must be confirmed using an appropriate test such as RIBA (Recombinant Immunoblotting Assay) or equivalent. The test is intended for healthcare professionals' use and trained healthcare workers as a tool to diagnose clinical conditions related to infection with Hepatitis C Virus.

SUMMARY

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

TEST PRINCIPLE

A HCV recombinant 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 HCV recombinant antigen and generate a complex. As the mixture moves along the test strip, the complex gets captured by a recombinant HCV antigen (containing Core, NS2, NS3, NS4, NS5 segments) immobilized on the membrane, forming a colored test band in the test region. A negative specimen does not produce a test line due to the absence of colloidal gold conjugate/HCV antibody complex. Regardless if HCV antibodies exist in specimens, the unbound gold marked protein will bind to the sheep anti-mouse IgG in the control band, forming a colored band in the control region. To ensure assay validity, a colored control band in the control region appears at the end of test procedure regardless of test result [1-2].

STORAGE CONDITIONS AND STABILITY

The shelf life of Rapid Anti-HCV Test is 24 months from date of manufacturing. Unused kits shall be kept at 2-30℃. If it is kept in refrigeration, the kit shall be taken out of the refrigerator and allowed to recover to room temperature (10-30℃) before use. Sample diluent shall be used within 8 weeks after opening.

⚠ WARNINGS AND PRECAUTIONARY MEASURES [3-4]

1. The test is intended for in vitro diagnostic use only.
2. This test is a rapid test used as an aid for diagnosis and all positive results must be confirmed using an appropriate test such as RIBA (Recombinant Immunoblotting Assay) or equivalent.
3. All specimens shall be treated as potentially infectious. Gloves and protective clothing must be worn when handling specimens.
4. Operate according to standard safety precautions when disposing biohazardous materials.
5. Used test cassette must be decontaminated before being discarded.
6. DO NOT use expired reagents or test cassettes.
7. DO NOT interchange reagents among kits with different lot No..
8. DO NOT use the Disposable Safety Lancets if the cap is already pulled off.
9. DO NOT reuse test cassettes and any disposable accessories. (test cassette, plastic dropper, Sample diluents, Disposable Safety Lancets, Disposable Swabs, desiccant).
10. DO NOT use the test cassette if the foil pouch is damaged or broken.
11. DO NOT use the Disposable Swabs if the pouch is damaged.
12. 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 quantities used in this kit are small, nevertheless when disposing of sodium azide containing materials, they should be flushed away with relatively large quantities of water to prevent metal azide building up in plumbing system.

REAGENTS AND MATERIALS PROVIDED

Component	25 tests (product code ITP01152-TC25)	40 tests (product code ITP01152-TC40)	10 tests (product code ITP01153-TC10)	40 tests (product code ITP01153-TC40)
Test cassette	25	40	10	40
Plastic pipette	25	40	10	40
Sample Diluents	3×2mL bottles	4×2mL bottles	10× 0.5mL bottles	4×2mL bottles

Component	25 tests (product code ITP01152-TC25)	40 tests (product code ITP01152-TC40)	10 tests (product code ITP01153-TC10)	40 tests (product code ITP01153-TC40)
Disposable Safety Lancets	Not provided	Not provided	10	40
Disposable Swabs	Not provided	Not provided	10	40
Package Insert	1	1	1	1

Note: information of Disposable Safety Lancets and Disposable Swabs

Accessory	Manufacturer	Authorized Representative	CE mark
Disposable Safety Lancets	SteriLance Medical (Suzhou) Inc. No.68 Litanghe Road, Xiangcheng, Suzhou, China	EMERGO EUROPE Molenstraat 15, 2513 BH, The Hague, The Netherlands	CE 0197
Disposable Swabs			CE

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch
- Blood sampling tools (lancet, capillary, venous puncture device, etc.)
- Biohazard waste container
- Disposable gloves

SPECIMEN COLLECTION AND STORAGE 5

Fingerstick whole blood

1. Rub the finger to stimulate blood flow, clean the subject's finger with the Disposable Swabs (antiseptic alcohol swab) and leave the finger to dry in the air or wipe dry with a sterile gauze. Prick the skin of the fingertip side with the Safety Lancets (for the provided Disposable Safety Lancets: twist off the protective cap and remove it. Place Lancet firmly on the finger and lancet will trigger), and keep the fingertip face down, lightly press the bleeding point (avoid excessive bleeding). Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
2. Collect the blood specimen with the plastic pipette provided. (Gently squeeze the bulb of the dropper and touch the tip to a drop of blood. Release the bulb to draw up the blood.)

Venous whole blood

1. With standard venous blood sampling process, collect whole blood specimen in a tube with any of the regular anticoagulants (EDTA, heparin sodium or sodium citrate). Other anticoagulants may lead to incorrect results. The whole blood specimen can be stored at 2-8ºC for 3 days, if it is not used immediately after being sampled. Before testing, mix the blood tube by shaking gently or shaker to ensure a homogeneous specimen.
2. Collect the blood specimen with the plastic pipette provided. (Gently squeeze the bulb of the dropper and touch the tip to a drop of blood. Release the bulb to draw up the blood.)

Serum or plasma

1. Serum
   With standard venous blood sampling process, collect whole blood specimen in a tube without any of the regular anticoagulants (EDTA, heparin sodium or sodium citrate). Keep for 30 minutes for blood coagulation and obtain serum specimen of supernatant after centrifuging (at least 5 minutes at 3000rpm).
2. Plasma
   With a standard process for venous blood sampling, collect whole blood specimen in a tube with any of the regular anticoagulants (EDTA, heparin sodium or sodium citrate). Obtain plasma specimen after centrifuging (at least 5 minutes a 3000rpm).

Notes:

(1) Serum or plasma specimens shall be kept refrigerated at 2-8ºC. For specimens stored over 7 days, freezing at - 20ºC or below is recommended (avoid multiple free-thaw cycles, 3 at most). Frozen specimens shall be thawed and allowed to reach room temperature (10-30ºC) before testing.

(2) Serum or plasma specimen containing precipitate may lead to inconsistent results. Such specimens have to be cleared before use by centrifugation.

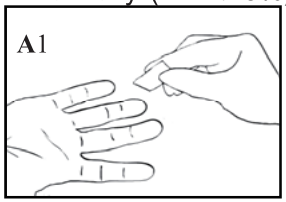
(3) This reagent is suitable for whole blood, serum or plasma specimens. It will not obtain an accurate result if used for other types of specimens, for example saliva, urine etc.

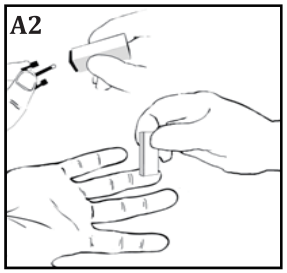
TEST PROCEDURE

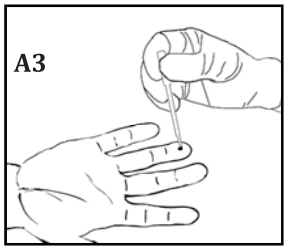
Do not open the pouch until ready to perform a test, and the single-use test is suggested to be used under low environment humidity (RH≤70%) within 1 hour after pouch open.

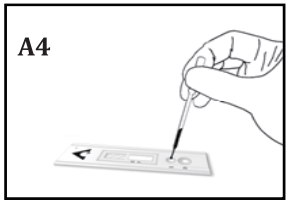
Test procedure for Fingertip whole blood

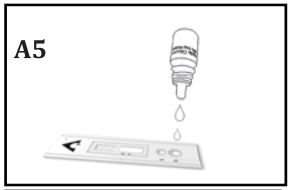
1. Leave all reagents and specimens to reach room temperature (10-30℃);
2. Take out the test cassette from the aluminum foil pouch and put it on a clean and dry surface;
3. Mark the patient ID number on the test cassette;
4. Rub the finger to stimulate blood flow, clean the subject's finger with the Disposable Swabs (antiseptic alcohol swab) and leave the finger to dry in the air or wipe dry with a sterile gauze. (Figure A1) ;
5. Prick the skin of the fingertip side with the Safety Lancets (for the provided Disposable Safety Lancets: twist off the protective cap and remove it. Place Lancet firmly on the finger and lancet will trigger), and keep the fingertip face down, lightly press the bleeding point (avoid excessive bleeding). Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form. (Figure A2) ;
6. Collect the blood specimen with the plastic pipette provided. (Gently squeeze the bulb of the dropper and touch the tip to a drop of blood. Release the bulb to draw up the blood.) (Figure A3) ;
7. Add 10μl (or 1 drop using the plastic pipette provided in the kit) of fingertip whole blood to Sample Port (Port S) on the test cassette (Figure A4) ;
8. Then add 2 drops (2×50μl) of sample diluent to the Diluents Port (Port D)(Figure A5) immediately;
9. Wait for at least 15 minutes (and 20 minutes at most) to read the result (Figure A6).

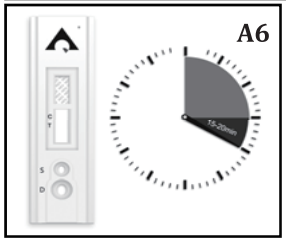






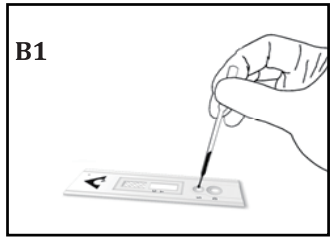


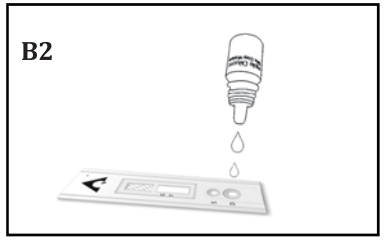


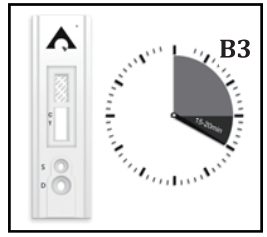


Test procedure for Venous whole blood

1. Leave all reagents and specimen to reach room temperature (10-30ºC);
2. Take the test cassette out of the aluminum foil pouch and put it on a clean and dry surface;
3. Mark the patient ID number on the test cassette;
4. Add 10μl (or 1 drop using the plastic pipette provided in the kit) of venous whole blood to Sample Port (Port S) on the test cassette (Figure B1) ;
5. Then add 2 drops (2×50μl) of sample diluent to the Diluents Port (Port D) immediately (Figure B2) ;
6. Wait for at least 15 minutes (and 20 minutes at most) to read the result (Figure B3).

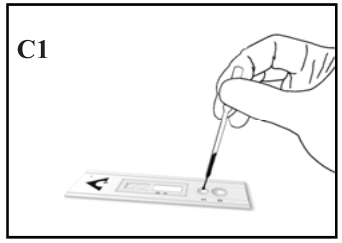


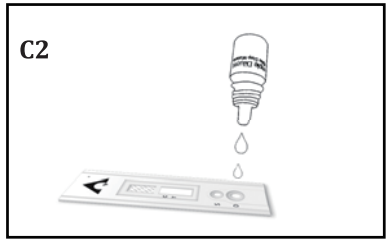


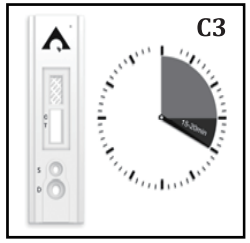


Test procedure for Serum or plasma

1. Leave all reagents and specimen to reach room temperature (10-30ºC);
2. Take the test cassette out of the aluminum foil pouch and put it on a clean and dry surface;
3. Mark the patient ID number on the test cassette;
4. Add 10μl (or 1 drop using the plastic pipette provided in the kit) of serum or plasma to Sample Port (Port S) on the test cassette (Figure C1);
5. Then add 2 drops (2×50μl) of sample diluents to the Diluents Port (Port D) immediately (Figure C2) ;
6. Wait for at least 15 minutes (and 20 minutes at most) to read the result (Figure C3);







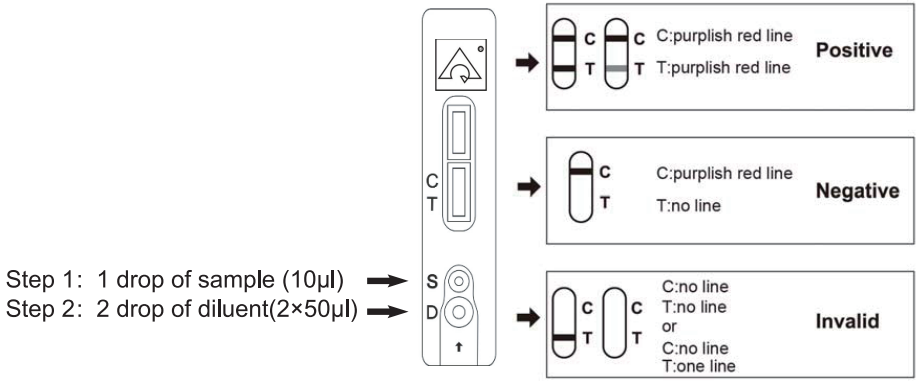
⚠ **Caution: Always apply specimen with a new and clean plastic pipette to avoid cross-contamination.**

It is recommended to run a known positive control and negative control at regular time intervals to ensure validity of the assay.

Notes:

1. Normally the positive results detected in 15-20 minutes do not change any more. Nevertheless, DO NOT interpret test results after 20 minutes.
2. Positive specimens with a high concentration of HCV antibody may display results already before 15 minutes.
3. Negative results cannot rule out the possibility of exposure to HCV infection.

TEST RESULT AND INTERPRETATION



1. Positive: Both purplish red test band and purplish red control band appear on the membrane.
   Caution: if presence of any test line, no matter how faint, the test results shall be considered positive.
2. Negative: purplish red control band only appears on control line. No band on test line indicates a negative result.
3. Invalid: The test is considered invalid if there is no purplish red control band. Use new assay to repeat the test.

Note: 1.It is normal to have a slightly lightened control band with very strong positive specimens as long as it is distinctly visible.

2.This test is a rapid test used as an aid for diagnosis and all positive results must be confirmed using an appropriate test such as RIBA (Recombinant Immunoblotting Assay) or equivalent.

PERFORMANCE CHARACTERISTICS [7-8]

The performance of the Rapid Anti-HCV Test has been evaluated by testing specimens from blood donors, from hospitalized patients and commercial seroconversion panels. The performance evaluations were conducted in three European sites to verify compliance with the requirements of the Common Technical Specifications 2002/364/EC, as amended by Commission Decision 2009/108/EC.

1. Sensitivity

1.1 Performance on HCV positive specimens

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

Table 1.1 Test results on HCV positive specimens

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)
	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 univocally detected by Rapid Anti-HCV Test.

1.2 Performance on specimens with known HCV genotype

EDTA plasma specimens from Dutch patients (n=93) with known HCV-genotype based on Versant HCV LIPA 2.0 assay, were tested with the Rapid Anti-HCV test. All specimens revealed positive Rapid Anti-HCV test results with clear reaction bands observed.

Table 1.2 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

It is concluded that different HCV genotypes are detected well by the Rapid Anti-HCV Test.

2. Performance on commercial seroconversion panels

Table 2 Test results with HCV Seroconversion Panels

Panel ID	Rapid Anti-HCV Test	ChLIA A	ChLIA B	ChLIA C	ELISA A	ELISA B	ELISA C	ELISA D
PHV904	4/7	4/7	4/7	3/7	3/7	3/7	3/7	
PHV905	6/9	6/9	6/9	3/9	3/9	4/9	4/9	
PHV907	3/7	3/7	4/7	3/7	3/7	3/7		
PHV908	10/13	10/13		8/13	10/13	8/13		
PHV910	3/5	3/5		3/5	3/5	3/5		
PHV911	4/5						3/5	
PHV913	2/4						0/4	0/4
PHV914	5/9	5/9	5/9	3/9	4/9	4/9	3/9	3/9
PHV915	1/4						2/4	2/4
PHV916	3/8	3/8	4/8	3/8	0/8	2/8		
PHV918	2/8	2/8	1/8	1/8	2/8	1/8	2/8	2/8
PHV919	3/7	4/7	4/7	3/7	3/7		3/7	3/7
PHV920	7/10	7/10	7/10	7/10	7/10	6/10	6/10	7/10
PHV921	9/11	9/11	10/11	9/11		7/11		
6212	8/9	8/9	8/9	8/9	6/9	7/9		
6213	3/12	3/12		2/12	2/12	2/12	2/12	3/12
6214	6/13	6/13	4/13	5/13	3/13	5/13	4/13	3/13
6224	0/6						0/6	0/6
6226	4/12	4/12		4/12	3/12	3/12	3/12	
6227	2/7			2/7	2/7	2/7		
6228	4/12	4/12	3/12	4/12	0/12	3/12	3/12	0/12
6229	4/8	4/8	4/8	4/8	2/8	2/8	3/8	3/8
9044	2/6	2/6	3/6	2/6	1/6	2/6	2/6	2/6
9045	2/8						1/8	2/8
9047	4/10	4/10	4/10	4/10	3/10	4/10	4/10	4/10
9054	0/10*						1/10	1/10
9058	0/5*						1/5	

*: a very faint reaction was observed on the first negative specimen

Overall, in early infection Rapid Anti-HCV Test shows a sensitivity that is similar to that of current CE marked anti-HCV screening assays.

3. Specificity

Table 3 Performance on HCV negative specimens

Population	Specimen Type	Rapid Anti-HCV Test			
		Negative	Positive	Total	Specificity
Europe	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)

4. Cross-reactivity

Table 4 Test results on potentially cross-reacting specimens

Potentially 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

5. Performance on fresh specimens

25 fresh specimens spiked with an amount of anti-HCV antibodies were tested on day 0 and after 1, 2, 3 and 4 days of storage at 4°C.

No differences were observed on the results obtained on the fresh specimens and the same specimens stored for 1 to 4 days at 4°C.

Table 5 Test results with fresh specimens

	Day 0	Day 1	Day 2	Day 3	Day 4
Negative specimens	25/25	ND	ND	ND	ND
Spiked specimens	25/25	25/25	25/25	25/25	25/25

6. Performance on different types of specimens

Whole blood:

- Sensitivity obtained on 100 pairs of whole blood and plasma specimens of Positive patients were 100% for both specimen types. (refer to Table 1)
- specificity obtained on 500 whole blood specimens of blood donors was 100%. (refer to Table 3)

Serum / plasma types: serum, plasma (EDTA, Heparin and Citrate)

Table 6.1 Plasma/ Serum couples comparison test with HCV-negative specimens

	EDTA plasma	Heparin plasma	Citrate plasma	Serum
Tested	25	25	25	25
Test negative	25	25	25	25
Test positive	0	0	0	0
Specificity	100%	100%	100%	100%

Table 6.2 Plasma/ Serum couples comparison test with HCV-positive specimens

	EDTA plasma	Heparin plasma	Citrate plasma	Serum
Tested	25	25	25	25
Test negative	0	0	0	0
Test positive	25	25	25	25
Sensitivity	100%	100%	100%	100%

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

Venous whole blood/ Fingerstick whole blood

Table 6.3 Venous whole blood/ Fingerstick whole blood comparison test with HCV-positive &HCV-negative specimens

	HCV-positive specimens		HCV-negative specimens	
	Venous whole blood	Fingerstick whole blood	Venous whole blood	Fingerstick whole blood
Specimens Tested	25	25	25	25
Test negative	0	0	25	25
Test positive	25	25	0	0
Concordance rate	100%	100%	100%	100%

From the above information, it is concluded that Rapid Anti-HCV Test gives identical test results for specimen types serum, plasma, venous whole blood and fingerstick whole blood.

LIMITATIONS

1. Only specimens with good fluidity and without hemolysis can be used with this test;
2. Use of fresh specimen is recommended. Refrigerated specimens and frozen specimens can also be used after being allowed to recover to room temperature and full homogeneity. Do not freeze and thaw whole blood specimen.
3. This test is a rapid test used as an aid for diagnosis and all positive results must be confirmed using an appropriate test such as RIBA (Recombinant Immunoblotting Assay) or equivalent.
4. This test may generate false negative results in case of very low antibody concentrations.

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