LumiQuick Diagnostics, Inc.
2946 Scott Blvd., Santa Clara, CA 95054, USA

Tel: 1-408-855-0061
Fax: 1-408-855-0063
E-mail: info@lumiquick.com
Website: www.lumiquick.com

LETTER OF AUTHORIZATION

We, LumiQuick Diagnostics, Inc., having a registered office at 2946 Scott Blvd, Santa Clara, CA 95054, USA assign SRL SANMEDICO, having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as our authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This letter is valid through December 31, 2023 and will automatically renewed upon the agreement of both companies. Should you have questions, please contact us.

Best regards,

Charles Yu

President

Date: January 19, 2022

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Digitally signed by Monastîrschii Viorica
Date: 2022.04.21 09:37:06 EEST
Reason: MoldSign Signature
Location: Moldova

EMERGO EUROPE

24 March 2009

Mr. Jeff Wang
LumiQuick Diagnostics, Inc.
2946 Scott Blvd.
Santa Clara, CA 95054

Dear Mr.Jeff Wang:

I am writing to inform you that today, we have notified by registered mail the Competent Authority in the following countries:

Austria	Bulgaria	Cyprus	Czech Republic	Denmark	Estonia
Finland	France	Germany	Greece	Hungary	Iceland
Ireland	Italy	Latvia	Liechtenstein	Lithuania	Luxembourg
Malta	The Netherlands		Norway	Poland	Portugal
Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland
United Kingdom					

With this notification, LumiQuick Diagnostics, Inc. has met the requirements of the In-vitro Diagnostics Directive, 98/79/EC for the following devices:

- Adeno/Rota Virus
- Cardiac Marker
- Dengue IgG/IgM Combo (registered only in Italy and The Netherlands)
- Drugs of Abuse
- Fecal Occult Blood (registered only in Italy and The Netherlands)
- H. Pylori Ab/Ag
- HCG
- Legionella (registered only in Italy and The Netherlands)
- LH (registered only in Italy and The Netherlands)
- Strep A (registered only in Italy and The Netherlands)

As of today and without any further notice from the respective Competent Authorities, LumiQuick Diagnostics, Inc. can consider the respective devices and Authorized Representative as officially registered.

If you have any questions, please do not hesitate to contact me.

Yours sincerely,

Rene van de Zande
President & CEO
Emergo Europe

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Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	**Model/number**
Fecal Occult Blood Test Devices	
QuickProfile Fecal Occult Blood Test Card	72001
QuickProfile Fecal Occult Blood Test Strip	72006

MANUFACTURER		
Name of company	**Address**	**Representative**
LumiQuick Diagnostics, Inc.	2946 Scott Blvd. Santa Clara, CA 95054 USA	Jeff Wang

AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

CONFORMITY ASSESSMENT		
Device classification	**Route to compliance**	**Standards applied**
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	ISO 13485:2003

LumiQuick Diagnostics, Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Jeff Wang

TITLE: Quality Systems Manager **SIGNATURE:**

DATE: 28/04/2017

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E-mail: info@LumiQuick.com
Web: www.lumiquick.com

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	**Model/number**
Infectious diseases	
HIV I&II Test Strip	71001
HIV I&II Test Card	71002
HCV Antibody Test Card	71030
HBsAg Test Card	71004

MANUFACTURER		
Name of company	**Address**	**Representative**
LumiQuick Diagnostics, Inc.	2946 Scott Blvd. Santa Clara, CA 95054 USA	Jeff C. Wang

AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Molenstraat 15 2513 BH The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax service@emergogroup.com

CONFORMITY ASSESSMENT		
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Class: Self-Certify		ISO 13485:2003

LumiQuick Diagnostics, Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Jeff C. Wang

TITLE: Quality Systems Manager **SIGNATURE:** JWang Date: 2017.02.23 11:59:53 -08'00'

DATE: 23/02/2017

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

LumiQuick Diagnostics, Inc.
2946 Scott Blvd
Santa Clara
California
95054
USA

Holds Certificate No: **FM 574919**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development, manufacture and distribution of in vitro diagnostics test kits and reagents used in the diagnosis and management of disease status, including Infectious Diseases tests, Drugs of Abuse tests, Cardiac Monitor tests, Cancer Marker tests, Fertility Hormone tests, ELISA tests & Urine Chemistry tests.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2011-10-20
Latest Revision Date: 2020-08-31

Effective Date: 2020-10-20
Expiry Date: 2023-10-19

...making excellence a habit.™

LumiQuick Diagnostics, Inc
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CERTIFICATE OF ANALYSIS

Product Information

Part Number:	71030
Product Name:	QuickProfile™ HCV Antibody Test Card
Lot Number:	22011110
Quantity:	6015 Tests
Exp. Date:	2024-01
Integrity Test:	Pass

Assay Results

Controls	No. Tested	No. Passed	No. Failed
Negative	20	20	0
Weak Positive	20	20	0
Positive	20	20	0

The lot (Check one) ✓ passed _____ fails QC test

Authorized signature: Lin Bin Date: 2022-01-30

Quality Systems Manager

LumiQuick Diagnostics, Inc
2946 Scott Blvd.
Santa Clara, CA 95054
Tel. 408-855-0061, Fax 408-855-0063

CERTIFICATE OF ANALYSIS

Product Information

Part Number:	72001
Product Name:	QuickProfile™ Fecal Occult Blood Test Card
Lot Number:	22011111
Quantity:	2015 Tests
Exp. Date:	2024-01
Integrity Test:	Pass

Assay Results

Controls	No. Tested	No. Passed	No. Failed
Negative	9	9	0
Weak Positive	13	13	0
Positive	10	10	0

The lot (Check one) ✓ passed _____ fails QC test

Authorized signature: Lin Bin Date: 2022-01-30

Quality Systems Manager

LumiQuick

DIAGNOSTICS, INC.

QUICK PROFILE™ FECAL OCCULT BLOOD TEST CARD

FOR THE QUALITATIVE ASSESSMENT OF HUMAN HEMOGLOBIN IN FECES

CE

Catalog No.: 72001

For In-Vitro Diagnostic Use

INTENDED USE

QuickProfile™ Fecal Occult Blood test is a qualitative test that detects human hemoglobin in human fecal specimens. The test is a visual one step, in-vitro assay. It is intended for professional use to help diagnose gastrointestinal bleeding.

SUMMARY AND EXPLANATION

Colorectal cancer is the third most common cancer in the world. "Fecal occult blood" is generally defined as a blood loss of less than 50 mL/d. The appearance of occult blood in human fecal specimen is often associated with gastrointestinal diseases which might cause colorectal cancer if not treated promptly and properly. The traditional guaiac-based method lacks sensitivity and specificity, and has diet restrictions prior to the testing.

QuickProfile™ Fecal Occult Blood Test uses the technology of immunochromatographic sandwich assay. The test is more sensitive and more specific than the traditional guaiac assay. It is easier to interpret the result. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

TEST PRINCIPLE

QuickProfile™ Fecal Occult Blood Test is composed of two units, a fecal collection tube and a test device. A fecal specimen is collected in the collection tube containing sample extraction buffer, and then added to the test device. When sample is added to sample pad, it moves through the conjugate pad and mobilizes the gold anti-h hemoglobin antibody conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-h hemoglobin antibody that is coated on the test region. If h hemoglobin is present at levels of 50 ng/mL or greater, the result is the formation of a colored band in the test region. If there is no h hemoglobin in the sample, the area will remain colorless. The sample continues to move to the control area where goat anti-mouse IgG antibody will capture gold-antibody conjugate to form a pink to purple color, indicating the test is working and the result is valid.

MATERIAL PROVIDED

1. QuickProfile™ Fecal Occult Blood Test device
   Test zone: contains mice monoclonal anti-hemoglobin antibody.
   Control zone: contains goat anti-mouse IgG antibody.
   Conjugate pad: contains gold-mice monoclonal anti-hemoglobin antibody conjugate.
2. Fecal specimen collection tube
   The collection tube contains 2 ml of buffer.
3. Instructions for use

MATERIALS REQUIRED BUT NOT SUPPLIED

Timer or clock.

STORAGE

1. Store the test device in the original sealed pouch and the fecal specimen collection tube at 4 to 30°C. **Do Not Freeze**.
2. The expiration date given was established under these storage conditions.
3. The test device should remain in its original sealed pouch until ready for us.
4. The device is designed for single use. Once the pouch is opened, the device must be tested as soon as possible and cannot be reused.

PRECAUTIONS

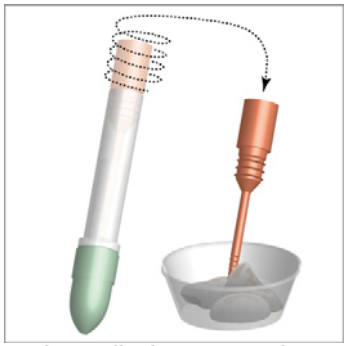
1. For in-vitro diagnostic use only.
2. Do not use product beyond the expiration date.
3. Handle all specimens as potentially infectious.

PATIENT PREPARATION

1. Specimen should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine.
2. Alcohol, aspirin and other medications, taken in excess, may cause gastrointestinal irritation resulting in occult bleeding. Such substances should be discontinued at least 48 hours prior to testing.
3. Dietary restrictions are not necessary.

SPECIMEN COLLECTION WITH SAMPLE TUBE TYPE I

1. Stool specimens can be collected at any time of the day.
2. Collect a random sample of feces in a clean, dry receptacle.
3. Unscrew the bottom cap (red end) of the collection tube and remove the applicator stick.
4. Insert the stick into the fecal specimen at several different sites.
5. Insert the sampled applicator back to the tube and tighten the bottom (red end) securely. The hold that only allows the stick goes through will prevent the access sample from getting into the tube.
6. Shake the tubes with bottom cap (red end) vigorously for about 5 seconds to release and disperse the stool sample into the collection buffer.



Specimen collection Steps 3 and 4

Specimen collection Steps 5 and 6

SPECIMEN COLLECTION WITH SAMPLE TUBE TYPE II

1. Stool specimens can be collected at any time of the day.
2. Collect a random sample of feces in a clean, dry receptacle.
3. Unscrew the cap (red end) of the collection tube and remove the applicator stick.
4. Insert the stick into the fecal specimen at several different sites.
5. Insert the sampled applicator back to the tube and tighten the cap securely.
6. Shake the tubes vigorously for about 5 seconds to release and disperse the stool sample into the collection buffer.

Specimen collection Steps 3 and 4

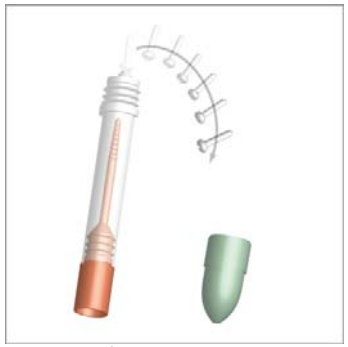
Specimen collection Steps 5 and 6

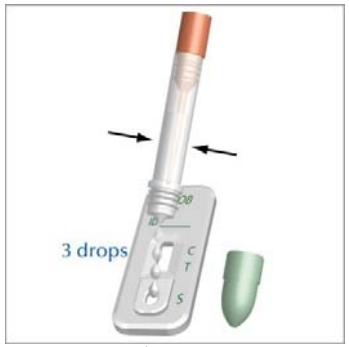
SPECIMEN STABILITY
The sample can be stored at room temperature (8 - 30°C) up to seven days if not immediately tested. If the condition allowed, the sample can also be refrigerated (2 – 8°C) for better storage.

QUALITY CONTROL
1. It is recommended that a positive control, with a level between 50–200 ng/mL h hemoglobin and a negative control, 0 ng/mL h hemoglobin, be used. Control materials, which are not provided with this test kit, are commercially available.
2. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.

You should always follow local, state and federal guidelines for running QC.

PROCEDURE
1. Bring all materials and specimens to room temperature (8–30ºC).
2. Remove the test card from the sealed foil pouch.
3. 3.1 If collection tube Type I is used, remove the tip protection cap (green). Holding the tube upright with tip pointed toward the direction away from the test performer, Snap off the tip.
   3.2 If collection tube Type II is used, hold the tube upright with tip pointed toward the direction away from the test performer, Snap off the tip.
4. Hold the tube in a vertical position over the sample well of the test card and deliver 3 drops (120-150 μL) of sample into the sample well marked as "S" on the cassette.
5. Read the results between 3 and 10 minutes.
   Note: Results read after 10 minutes may not be accurate.


Assay Procedure Step 3.1



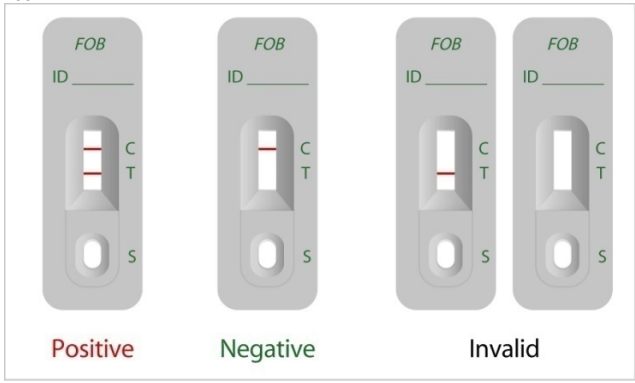
Assay Procedure Step 4

Assay Procedure Step 3.2

Assay Procedure Step 4

INTERPRETATION OF RESULTS
Positive:
If two colored bands are visible within 3 minutes, the test result is positive and valid.
Note: Specimens containing very low levels of h hemoglobin may develop two colored bands over 10 minutes.

Negative:
If test area has no colored band and the control area displays a colored band, the result is negative and valid.
Invalid result:
The test result is invalid if a colored band does not form in the control region. The sample must be retested using a new test device.



LIMITATIONS OF THE PROCEDURE
1. A number of conditions, as mentioned in "Patient Preparation", can cause false positive results.
2. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS
A. Sensitivity:
The analytical sensitivity of the test is 50 ng/mL h hemoglobin or 12.5 μg h hemoglobin/g feces.

B. Specificity:
The test is specific to human hemoglobin. Samples containing the following substances were tested on both positive and negative controls with no effect on test results.

Substances	Concentrations
Beef hemoglobin	1 mg/mL
Chicken hemoglobin	1 mg/mL
Goat hemoglobin	1 mg/mL
Horse hemoglobin	1 mg/mL
Pork hemoglobin	1 mg/mL
Rabbit hemoglobin	1 mg/mL
Duck hemoglobin	1 mg/mL
Dog hemoglobin	1 mg/mL
Horseredish peroxidase	1 mg/mL

C. Interference testing:
The following substances were added to h hemoglobin free and 50 ng/mL controls. No interference was found with any of the substances at the following concentrations:

Acetaminophen	20 mg/dL
Acetylsalicyclic acid	20 mg/dL
Ampicillin	40 mg/dL
Ascorbic acid	40 mg/dL
Atropine	40 mg/dL
Caffeine	40 mg/dL
Gentisic acid	40 mg/dL
Glucose	2000 mg/dL
Human albumin	2000 mg/dL
Urea	4000 mg/dL
Uric acid	10 mg/dL

REFERENCES

1. Simon J.B. “Occult blood screening for colorectal carcinoma: a critical review”, Gastroenterology, Vol. 88 820, 1985.
2. Woo. H. and McDonald C. “Detection of fecal occult blood using monoclonal antibodies”, Gasteroenterology society of Australia, Annual general Meeting. Melbourne, Victoria, Australia, May 1986.
3. Adams, E.C. and Layman, K.M. “Immunochemical confirmation of gastrointestinal bleeding”, Ann. Elin. Lab. Sci., Vol. 4 343, (1974).
4. Ribet, A., et al. “Occult-blood test and colorectal tumors”, Lancet, Vol. 1, 417, (1980).
5. Taranen, M.J., et al. “Immunological detection of fecal occult blood in colorectal cancer”, Br. J. Cancer, Vol. 49 141, (1984).

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Emergo Eurpoe
Molenstraat 15
2513 BH The Hague
The Netherlands

LumiQuick

DIAGNOSTICS, INC.

QuickProfile™ HCV ANTIBODY TEST

FOR THE QUALITATIVE ASSESSMENT OF HCV ANTIBODY
IN HUMAN SERUM, PLASMA OR WHOLE BLOOD

REF 71027 HCV Test Strip
REF 71030 HCV Test Card

For In Vitro Diagnostic Use Only

INTENDED USE

QuickProfile™ HCV Ab Test is a chromatographic immunoassay for qualitative detection of the antibodies against hepatitis C virus (HCV Ab) in human serum, plasma or whole blood samples. It is intended for professional use as an aid for diagnosis and management of patients related to infection with hepatitis C as well for primary screening of blood from volunteer donors.

SUMMARY

Hepatitis C virus (HCV) is an envelope, single stranded positive sense RNA (9.5 kb) virus belonging to the family of Flaviviridae. Six major genotypes and series of subtypes of HCV have been identified. Isolated in 1989, HCV is now recognized as the major cause for transfusion associated non-A, non-B hepatitis. The disease is characterized with acute and chronic form. More than 50% of the infected individuals develop severe, life threatening chronic hepatitis with liver cirrhosis and hepatocellular carcinomas. Since the introduction in 1990 of anti-HCV screening of blood donations, the incidence of this infection in transfusion recipients has been significantly reduced. Clinical studies show that significant amount of HCV infected individuals develop antibodies to NS5 non-structural protein of the virus. For this, the third generation tests include antigens from the NS5 region of the viral genome in addition to NS3 (c200), NS4 (c200) and the Core (c22). Third generation tests have improved sensitivity and shorten the time between infection with HCV and the appearance of detectable antibodies (window period) to 60 days.

TEST PRINCIPLE

QuickProfile™ HCV Ab Test employs a chromatographic lateral flow device in a strip or cassette format. Recombinant HCV antigens are immobilized at the Test Zone (T) and goat anti mouse IgG antibodies are immobilized at the Control Zone (C) on the nitrocellulose membrane. When the sample is added, it migrates by capillary diffusion and rehydrating the colloidal gold conjugated recombinant HCV antigens (Au-Ag) dried onto the fiberglass strip. If present in sample, HCV antibodies will bind the gold conjugated antigens forming complexes. These complexes will continue to migrate along the strip until the Test Zone (T) zone where they are captured by the HCV antigens to form a visible red line. The colloidal gold-mouse IgG is used as the indictor for control line. A red line formed by gold-mouse IgG and goat anti-mouse IgG at the Control Zone (C) indicates the validity of the test.

MATERIAL PROVIDED

1. QuickProfile™ HCV Ab Test
2. Sample buffer
3. Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

Clock or timer
Specimen collection container
Centrifuge
Biohazard waste container

STORAGE

The sealed pouches in the test kit may be stored between 4-30ºC for the duration of the shelf life as indicated on the pouch. The test must be used immediately after being removed from the sealed pouch.

PRECAUTIONS

1. This kit is for ***in vitro*** diagnostic use only.
2. This kit is for ***PROFESSIONAL*** use only.
3. Read the instructions carefully before performing the test.
4. This product does not contain any human source materials.
5. Do not use kit contents after the expiration date.
6. Handle all specimens as potentially infectious.
7. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. When the assay procedure is completed, dispose of specimens after autoclaving them at 121º C for at least 20 min. Alternatively, they can be treated with 0.5% Sodium Hypochlorite for 1-2 hours before disposal.
8. Do not pipette reagent by mouth and do not no smoke, eat or drink while performing assays.
9. Wear gloves during the whole procedure.

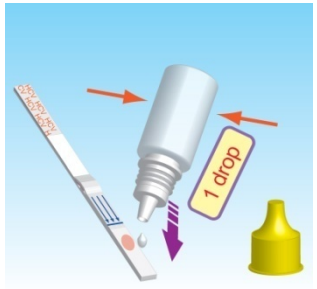
SPECIMEN COLLECTION AND PREPARATION

Fresh serum, plasma or whole blood samples can be used for this assay. Blood collected by venipuncture should be allowed to clot naturally and completely – the serum/plasma must be separated from the clot as early as possible as to avoid hemolysis of the red blood cell. Care should be taken to ensure that the serum samples are clear and not contaminated by microorganisms. Any visible particulate matter in the sample should be removed by centrifugation at 3000 RPM for at least 20 minutes at room temperature, or by filtration with 0.22u filters. Plasma samples collected into EDTA, sodium citrate or heparin may be tested, but highly lipaemic, icteric, or hemolized samples should not be used as they could give erroneous results in the assay. Do not inactivate samples by heat. This can cause deterioration of the target proteins in the sample.

ASSAY PROCEDURE

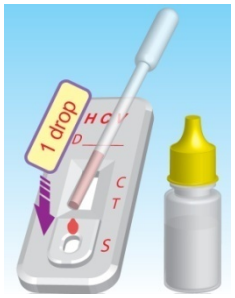
For HCV Test Strip (Catalog Number: 71027)

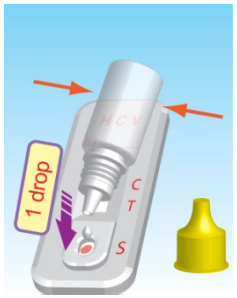
1. Allow the test strip and sample to reach room temperature if necessary.
2. Open the pouch, Take out the test strip and transfer pipet.
3. Using the transfer pipet to draw up the sample, dispense one drop (approx 40µl) specimen to the sample pad as shown in the illustration, and wait for a few seconds until the sample is completely absorbed by sample pad.
4. Add one drop (approx 40µl) sample buffer to the sample pad as shown in the illustration.
5. Read the results at 20 minutes.



For HCV Test Card (*Catalog Number: 71030*)

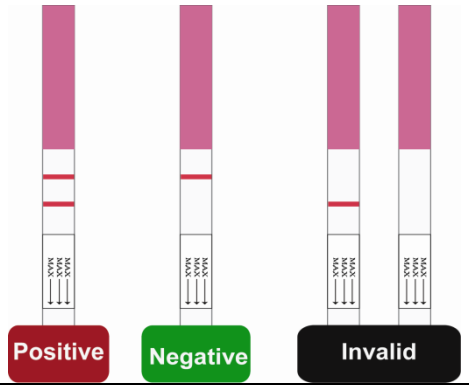
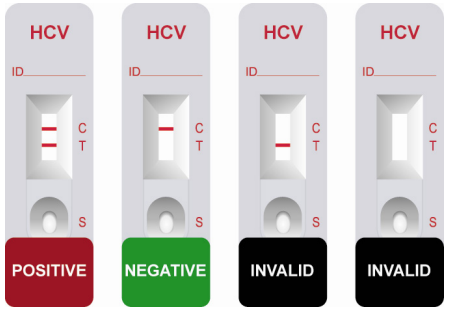
1. Allow the test card and sample to reach room temperature if necessary.
2. Open the pouch, Take out the test card and transfer pipet..
3. Using the transfer pipet to draw up the sample, dispense one drop (approximately 40µl) of specimen to the sample well marked as "**S**" and wait for a few seconds until the sample is completely absorbed by sample pad.
4. Add one drop (approx. 40 µl) sample buffer into the sample well marked as "**S**".
5. Read the results at 20 minutes.





Some positive samples may show positive results before 20 minutes.
Results after 30 minutes may not be accurate.

INTERPRETATION OF RESULTS

TEST STRIP		**Positive** If two color bands are visible within 20 minutes, the test is positive and valid. The test result can be read as soon as a distinct colored band appears in test zone and control zone respectively. It indicates that HCV Ab has been detected using QuickProfile™ HCV Ab Test.
TEST CARD		**NEGATIVE** Only one red line appears in the Control Zone (C), indicating that no HCV Ab have been detected with QuickProfile™ HCV Ab Test. However, this does not exclude the possibility for infection with HCV. **INVALID** One red line should always appear at Control Zone (C) if no red line appears in the Control Zone (C), the test is invalid. The sample must be re-tested using a new device

QUALITY CONTROL

1. The control band is an internal reagent for procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials are not provided with this test kit but may be commercially available.

LIMITATIONS

1. The test is for in vitro diagnostic use only.
2. Negative results do not rule out the possibility of hepatitis C exposure or infection. Infection through recent exposure to HCV may not be detectable.
3. The positive result obtained with QuickProfile™ HCV Ab Test alone cannot be the final diagnosis of hepatitis C infection. As in the case of all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test but should rather be made after all the clinical findings have been evaluated.
4. This test is intended ONLY for testing of individual serum, plasma or whole blood samples. DO NOT use it for testing of other body fluids or pooled blood samples.
5. The test is for qualitative detection of anti-HCV antibody in human serum, plasma or blood sample and does not indicate the quantity of the antibodies.

PERFORMANCE CHARACTERISTICS:

1. Accuracy

In clinical evaluation of the QuickProfile™ HCV Ab Test, 727 confirmed negative and 327 positive samples were tested. A sensitivity of 99.08% (324/327) and a specificity of 99.17% (721/727) were obtained.Overall, agreement with the Predicate Test is 99.15%.

	Predicate HCV Ab Test		
QuickProfile™ HCV Ab Test		Positive	Negative
	Positive	324	6
	Negative	3	721
	Agreement	99.08%	99.17%

2. Interference

No cross reactivity was observed with specimens from patients infected with HAV, HBV, HIV, HTLV, CMV, and TP.

REFERENCES

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2. Alter HJ., Purcell RH, Holland PV, et al. (1978) Transmissible agent in non-A, non-B hepatitis. Lancet I: 459-463.
3. Choo Q-L,Weiner AJ, Overby LR, Kuo G, Houghton M. (1990) Hepatitis C Virus: the major causative agent of viral non-A, non-B hepatitis. Br Med Bull 46: 423-441.
4. Engvall E, Perlmann P. (1971) Enzyme linked immunosorbent assay (ELISA): qualitative assay of IgG. Immunochemistry 8:871-874.

IVD 4°C 30°C

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