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

Digitally signed by Monastîrschii Viorica
Date: 2022.11.21 13:55:49 EET
Reason: MoldSign Signature
Location: Moldova

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

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

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	**Model/number**
H. Pylori Ab/Ag Test Devices	
QuickProfile H. Pylori Antigen Test Card	71020
QuickProfile H. Pylori Antibody Test Card Whole Blood	71024
QuickProfile H. Pylori Antibody Test Card-Serum	71046
QuickProfile H. Pylori Antigen Test Strip	71061
QuickProfile H. Pylori Antibody Serum Test Strip	71064
QuickProfile H. Pylori Antibody WB Test Strip	71086

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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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

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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.™

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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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LumiQuick
DIAGNOSTICS, INC.

QuickProfile™ HELICOBACTER PYLORI ANTIGEN TEST

Movies available at YouTube : www.youtube.com/lumiquickinc

Cat.# 71020

Immunochromatographic rapid assay for the Detection of Helicobacter pylori Antigens in Human Stool Specimens

INTENDED USE

QuickProfile™ H. pylori Antigen Test is an *in vitro* qualitative immunochromatographic assay for the rapid detection of *Helicobacter pylori* antigens in human stool specimen. This test is intended to aid in the diagnosis of *H. pylori* infection, to monitor the effectiveness of therapeutic treatment and to confirm the eradication of *H. pylori* in peptic ulcer patients.

INTRODUCTION

Helicobacter pylori is a corkscrew-shaped, gram-negative rod that lives in the mucous layer of the stomach. *H. pylori* infection is now accepted as the most common cause of gastritis, and is etiologically involved in gastric ulcer, duodenal ulcer, gastric adenocarcinoma and primary gastric *B*-cell lymphoma.[1,2]

The organism is very common, infecting at least half of the world's population. *H. pylori* infection is typically acquired in childhood. Once acquired, infection persists chronically, probably continuing in the stomach throughout life. The damage to gastric structure and function of stomach is constant and direct. Approximately one in six of *H. pylori* infections develop peptic ulcer disease and a small portion of *H. pylori* infection leads to gastric cancer.[3]

The diagnostic tests for *H. pylori* can be classified into two categories: Invasive and Noninvasive tests. Direct detection by invasive test procedures requires an endoscopy and biopsy specimens from antrum and stomach body.[4] The presence of *H. pylori* is then confirmed by direct culture, histological examination or rapid urease test. The endoscopy and biopsy specimens offer direct detection of active *H. pylori* infections. Although the procedure is highly specific and high positive predictive value, the cost and discomfort to the patients are very high.

The most widely available noninvasive test is probably the serological based test. The serology test detects *H. pylori* specific IgG antibody in patient serum with current or prior infection.[5,6] Serology test is a simple, convenient test with relative high sensitivity. The main limitation of serology test is the inability to distinguish current and past infections. Antibody may be present in the patient's serum long after eradication of the organism.[6] The urease breath test (UBT) with ^{14}C or ^{13}C labeled urea, is a noninvasive test based on the urease activity of the organism. UBT detects active *H. pylori* infection and is highly sensitive and specific. The UBT requires a high density and active bacteria and should not be performed until 4 weeks after therapy to allow residual bacterial to increase to a sufficient number for detection.[7]

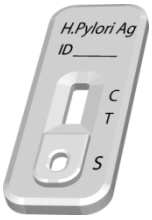
QuickProfile™ H. pylori Antigen Test is an immune-chromatographic assay that uses antibody- coated colloidal gold to detect the presence of *H. pylori* antigens in stool specimens. The test detects directly antigens in specimens for an active infection. The test is simple and easy to perform and the test results can be visually interpreted within 10 minutes

PRINCIPLE OF THE TEST

QuickProfile™ H. pylori Antigen Test is a sandwich solid phase immunochromatographic assay. To perform the test, an aliquot of diluted stool sample is added to the sample well of the test cassette. The sample flows through a label pad containing H. pylori antibody coupled to red-colored colloidal gold. If the sample contains H. pylori antigens, the antigen will bind to the antibody coated on the colloidal gold particles to form antigen-antibody-gold complexes. These complexes move on the nitrocellulose membrane by capillary action toward the test line region on which H. pylori specific antibodies are immobilized. As the complexes reach the test line, they will bind to the antibody on the membrane in the form of a line. A second red control line will always appear in the result window to indicate that the test has been correctly performed and the test device functions properly. If H. pylori antigen is not present or lower than the detection limit of the test, only the control line will be visible. If the control line does not develop, the test is invalid.

MATERIALS PROVIDED

1. QuickProfile™ H. Pylori Antigen test card
   Each cassette contains a test strip with H. pylori specific antibody on the test region of the membrane and colored H. pylori antibody-gold conjugate pad.



H. Pylori Antigen Test Card


Sample bottle

2. Sample bottle
   Each sample bottle contains 1.5 ml of stool specimen collection buffer. Store at 4-30°C

MATERIALS NOT PROVIDED

1. Specimen collection container
2. Timer.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Wear protective glove while handling kit components and test specimens.
3. Patient specimens and inactivated Positive Control may contain infectious agents and should be handled and disposed of as potential biohazards.
4. Do not use kit components beyond expiration date.
5. Dispose all used materials in appropriate container. Treat as potential biohazard.

STORAGE INSTRUCTION

1. The expiration date is indicated on the package label.
2. Sample Collection Tubes without introducing the sample can be stored at 4-30°C.
3. Test device can be stored at 4-30 °C.

SPECIMEN COLLECTION AND STORAGE

Stool specimens should be collected in containers that do not contain media, preservatives, animal serum or detergents as any of these additives may interfere with the QuickProfile™ H. pylori Antigen Test.

Specimens may be stored at 2-8°C for 3 days without interfering with the assay performance. For long-term storage of specimens, -20°C or colder is recommended. Repeated freezing and thawing of specimens is not recommended and may cause erroneous results. Do not store specimens in self-defrosting freezers.

REAGENT PREPARATION

Bring all reagents, including test device, to room temperature before use.

SPECIMEN PREPARATION

1. Unscrew the sample bottle, use the attached applicator stick attached on the cap to transfer small piece of stool (5-6 mm in diameter; approximately 100 mg – 200 mg/0.1-0.2 g) into the sample bottle containing specimen preparation buffer.
2. Replace the stick in the bottle and tighten securely. Mix stool sample with the buffer thoroughly by shaking the bottle for a few seconds.

   Note: Watery or diarrhea specimens are inappropriate for testing.

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PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Hold the sample bottle upright with the tip pointed away from the test performer, snap off the tip.
4. Hold the bottle in a vertical position over the sample well of the test card, deliver 3 drops (120 -150 μL) of diluted stool sample to the sample well.
5. Read the result within 10 to15 minutes. A strong positive sample may show result earlier.

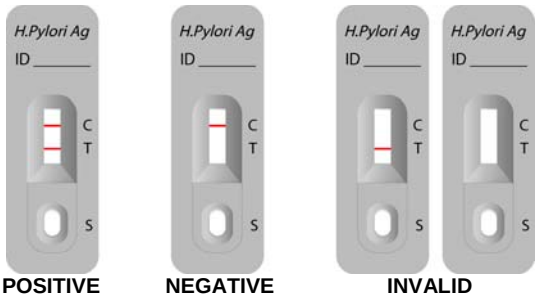
   Test results after 15 minutes may not be accurate.

INTERPRETATION OF RESULTS

Positive result: A distinct pink colored band appears on test line regions, in addition to a pink line on the control line region.

Negative result: No line appears in the test line region. A distinct pink line shows on the control line region.

Invalid: The control line next to the test line does not become visible within 10 minutes after the addition of the sample.



QUALITY CONTROL

1. 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.
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 qualitative detection of H. pylori antigen in stool sample and does not indicate the quantity of the antigens.
2. The test is for *in vitro* diagnostic use only.
3. The test result should be used only to evaluate with patient with signs and symptoms of gastrointestinal disease. A definitive clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Helicobacter pylori infects more than half the people in the world.[9] The prevalence of the infection varies among countries and among different groups within the same country.[10] The prevalence rate in the United State suggests an incidence of infection of 2%. The lifetime prevalence of peptic ulcer disease is about 12% in men and 9% in women.[11] Studies have found that more than 90% of patients with duodenal ulcer and 80% of patients with gastric ulcer are infected with *H. pylori*.[12,13]

QuickProfile™ H. pylori Antigen Test detects the presence of *H. pylori* antigens in stool specimens. Expected values for any given population should be determined for each laboratory. The positivity rate of any given laboratory may vary depending on geographic location, ethnic group, and living environment.

PERFORMANCE CHARACTERISTICS

Accuracy

QuickProfile™ Helicobacter pylori Antigen Test was evaluated on 1049 stool samples. The test results were compared with an approved predicate kit.

		Predicate Kit		Total
		Pos.	Neg.	
QuickProfile™ H.Pylori Ag Test	Pos.	508	11	519
	Neg.	5	525	530
Total		513	536	1049

Out of five hundred and thirteen (513) samples that were tested positive by the predicate kit, five hundred and eight (508) were positive on QuickProfile™ H. Pylori Antigen Test. Out of five hundred and thirty six (536) samples that were tested negative by the predicate kit, five hundred and twenty five (525) were negative on QuickProfile™ H. Pylori Antigen Test. Sixteen (16) samples that had disparity in results were verified by ELISA. Seven (7) samples had results in agreement with QuickProfile™ H. Pylori Antigen Test while nine (9) samples agreed with the predicate kit. The agreement with the predicate kit is summarized as below.

Agreement of positive = 508/513 = 99.03%
Agreement of Negative = 525/536 = 97.95%
Total Agreement = 1033/1049 = 98.47%

Assay Specificity
Following bacterial and viral strains were used to test the specificity of QuickProfile™ H. pylori Antigen Test. Positive and negative controls spiked with the bacteria or virus at the indicated concentration showed no interference on the test results.

Adenovirus type 40	$1x10^6$ $TCID_{50}$
Adenovirus type 41	$1x10^6$ $TCID_{50}$
Rotavirus Wa	$1x10^6$ $TCID_{50}$
Campylobacter jejuni	7.63×10^7CFU/ml
Candida albicans	$1x10^8$CFU/ml
Clostridium perfringens A	$1x10^8$CFU/ml
Citrobacter freundii	$1x10^8$CFU/ml
Enterococcus faecalis	$1x10^8$CFU/ml
Escherichia coli	$1x10^8$CFU/ml
Klebsiella pneumonia	$1x10^8$CFU/ml
Listeria monocytogenes	$1x10^8$CFU/ml
Moraxella catarrhalis	$9.9x10^6$CFU/ml
Neisseria gonorrhoeae	$1x10^8$CFU/ml
Pseudomonas aeruginosa	$1x10^8$CFU/ml
Stapylococcus epidermidis	$1x10^8$CFU/ml
Stapylococcus aureus	$1x10^8$CFU/ml
Shigella flexneri	$1x10^8$CFU/ml
Shigella sonnel	$1x10^8$CFU/ml
Streptococcus dysgalactiae	$1x10^8$CFU/ml
Streptococcus agalactiae	$1x10^8$CFU/ml
Streptococcus pyogenes	$1x10^8$CFU/ml

REFERENCES

1. Marshall, B.J. and Warren, J.R. Unidentified curved bacilli in the stomach of patients with gastric and peptic ulceration. *Lancer I*:1984: 1311-1314.
2. Graham K.S and Graham D.Y. 1999. Contemporary Diagnosis and Management of *H. pylori*-Associated Gastrointestinal Diseases, Handbooks in Health Care Co., Newtown, PA., 1999: 39-67.
3. Howden C.W. Clinical expressions of *Helicobacter pylori* infection. *Am J Med*; 1996;100:27S-33S.
4. El-Zimaity HM, Al-Assi MT, Genta RM, Graham DY. Confirmation of successful therapy of *Helicobacter pylori* infection: number and site of biopsies or a rapid urease test. *Am J Gastroenterol*. 1995;90:1962-1964.
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6. Cutler AF. Testing for *Helicobacter pylori* in clinical practice. *Am J. Med*. 1996;100:35S-41S.
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13. Tytgat GNJ, Noach LA, Rauws EAJ. *Helicobacter pylori* infection and duodenal ulcer disease. *Gastroenterol Clin North Am*. 1993;22:27-139.

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YouTube :
www.youtube.com/lumiquickinc

LumiQuick

DIAGNOSTICS, INC.

QUICK PROFILE™ HBsAg TEST

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

REF 71003 HBsAg Test Strip

REF 71004 HBsAg Test Card

For In Vitro Diagnostic Use Only

INTENDED USE

QuickProfile™ HBsAg Test is an immunochromatography assay for the qualitative detection of Hepatitis B virus surface antigen (HBsAg) in human serum, plasma or whole blood specimen.

TEST PRINCIPLE

QuickProfile™ HBsAg Test is a double antibody sandwich immunoassay. Colloidal gold conjugated anti-HBsAg antibody complexes are dry-immobilized in the test device. When the sample is added, it migrates by capillary diffusion through the strip re-hydrating the gold conjugate complexes. If present, HBsAg will react with the gold conjugate complexes forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by anti-HBsAg antibodies immobilized there and a visible red line appears. If there is no HBsAg in sample, no red line will appear in the Test Zone (T). The gold conjugate complexes will continue to migrate alone until they are captured in the Control Zone (C) by immobilized goat anti-mouse IgG antibody aggregating a red line, which indicates the validity of the test.

MATERIALS PROVIDED

1. QuickProfile™ HBsAg Test
2. Instructions for use
3. Disposable transfer pipet

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Whole blood or plasma: Vacutainer tube, or other appropriate tube, containing heparin or EDTA as an anticoagulant
2. Serum: Vacutainer tube, or other appropriate tube, without anticoagulant
3. Timer or clock

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 by mouth. Do not smoke, eat, or drink in areas where reagents or specimens are handled.

SPECIMEN COLLECTION AND PREPARATION

1. The serum, plasma or whole blood specimen should be collected under standard laboratory conditions.
2. Heat inactivation of specimens, which may cause hemolysis and protein denaturation, should be avoided.
3. Patient samples performed best when tested immediately after collection. If specimens are to be stored, the red blood cells should be removed to avoid hemolysis. If the sample cannot be tested within 24 hours, serum or plasma should be frozen until the test can be performed. Allow sample to reach room temperature before proceeding.
4. Sodium azide can be added as a preservative up to 0.1% without effecting the test results.

PROCEDURE

For HBsAg Test Strip (Catalog Number: 71003)

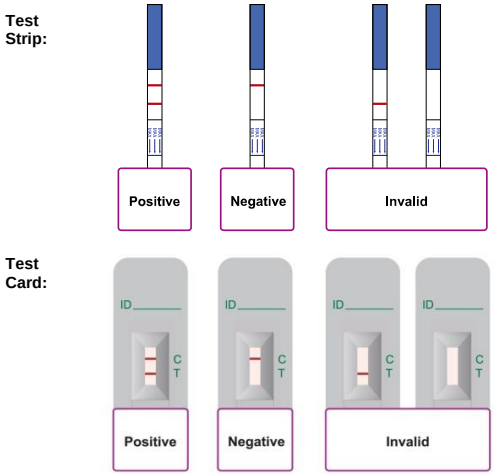
1. Bring all materials and specimens to room temperature.
2. Remove the test strip from the sealed foil pouch.
3. Label the test strip with specimen identity by writing the ID on the top label of the strip.
4. Place the test strip on a flat horizontal surface.
5. Use the transfer pipet to draw up the sample.
6. Hold the transfer pipet in a vertical position over the sample pad and dispense 2 drops (80-100 µl) of sample onto the sample pad.
7. Read the result at 20 minutes after adding the sample.

For HBsAg Test Card (Catalog Number: 71004)

1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Label the test card with specimen identity on the "ID ____ " area of the cassette.
4. Place the test card on a flat horizontal surface.
5. Use the transfer pipet to draw up the sample.
6. Hold the transfer pipet in a vertical position over the sample well and dispense 2 drops (80-100 µl) of sample into the sample well.
7. Read the result at 20 minutes after adding the sample.

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

INTERPRETATION OF RESULTS



Positive:
Two colored bands appear within 20 minutes. One colored band appears in the Control Zone (C) and another colored band appears in the Test Zone (T). The test result is positive and valid. No matter how faint the colored band appears in the Test Zone (T), the test result should be considered as positive result.

Negative:
One colored band appears in the Control Zone (C) within 20 minutes. No colored band appears in the Test Zone (T). The test result is negative and valid.

Invalid result:
No colored band appears in the Control Zone (C) within 20 minutes. The test result is invalid. Repeat the test with a new test 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 B exposure or infection. Infection through recent exposure to HBV may not be detectable.
3. The presumptive positive result obtained with QuickProfile™ HBsAg Test alone cannot be the final diagnosis of hepatitis B infection. As in 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 an individual serum, plasma or whole blood sample. DO NOT use it for testing of other body fluids or pooled blood samples.
5. The test is for qualitative detection of HBsAg in human serum, plasma or blood sample and does not indicate the quantity of the antibodies.

PERFORMANCE CHARACTERISTICS:

Sensitivity:
QuickProfile™ HBsAg Test can detect HBsAg with a concentration of 1.0 ng/ml.

Accuracy:
Twelve hundred and forty-nine (1249) ELISA confirmed samples, including four hundred and sixty-nine (469) positive samples and seven hundred and eighty (780) negative samples were used for the clinical evaluation of QuickProfile™ HBsAg Test. The results are summarized in the following table. The sensitivity, specificity and accuracy are all 99.6%.

	ELISA HBsAg Test		
QuickProfile™ HBsAg Test		Positive	Negative
	Positive	467	3
	Negative	2	777
	Agreement	99.6%	99.6%

BIBLIOGRAPHY

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IVD 4°C 30°C

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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.

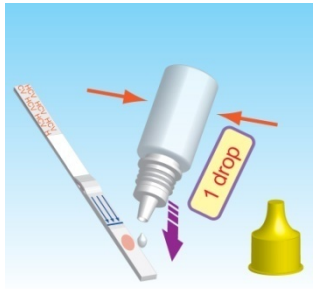
SPECIMEN COLLECTION AND PREPARATION

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

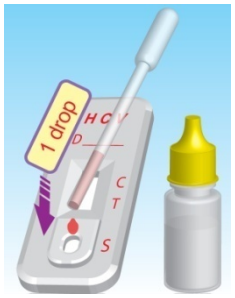
For HCV Test Strip (Catalog Number: 71027)

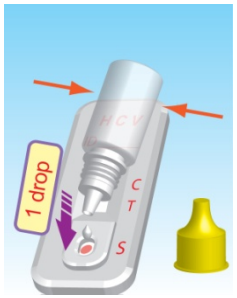
1. Allow the test strip and sample to reach room temperature if necessary.
2. Open the pouch, Take out the test strip and transfer pipet.
3. Using the transfer pipet to draw up the sample, dispense one drop (approx 40µl) specimen to the sample pad as shown in the illustration, and wait for a few seconds 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*)

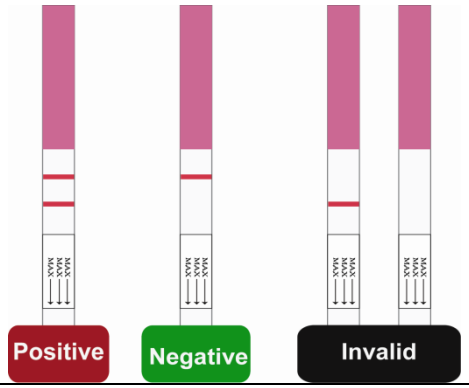
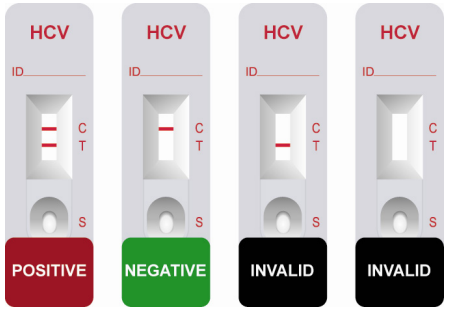
1. Allow the test card and sample to reach room temperature if necessary.
2. Open the pouch, Take out the test card and transfer pipet..
3. Using the transfer pipet to draw up the sample, dispense one drop (approximately 40µl) of specimen to the sample well marked as "**S**" and wait for a few seconds 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.

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Set de teste rapide QuickProfile™ pentru antigeni H.pylori

UTILIZAREA PREVĂZUTĂ

QuickProfile™ H.pylori este un in vitro imunotest ce utilizează metoda cromatografică pentru detectarea rapidă şi calitativă a antigenelor H.pylori în masele fecale umane. Rezultatele testului au intenţia de a ajuta în diagnosticarea infecţiei cu H.pylori, de a monitoriza eficacitatea tratamentului terapeutic şi confirmarea eradicării H.pylori la pacienţii cu ulcer peptic.

PRINCIPIU

Testul QuickProfile™ H.pylori Antigen este un imunotest tip sandwich ce utilizează metoda cromatografică. Pentru a petrece testul , se adaugă o probă diluată alicotă la caseta testului. Proba curge printr-un tampon(suport) - etichetă ce conţine anticorpi H.pylori cuplaţi cu aurul coloidal colorat în roşu. Dacă proba conţine antigeni H.pylori, antigenii se vor lega de anticorpii ce acoperă particulele de aur coloidal pentru a forma un complex de antigeni-anticorpi-aur. Aceste complexe se mişcă pe membrana de nitroceluloză prin acţiune capilară pîna la regiunea liniei de test pe care anticorpii specifici H.pylori sunt imobilizaţi. Pe măsură ce complexele ajung la linia de test, ele se vor lega de anticorpi pe membrană în formă de linie. O a doua linie roşie de control întotdeauna va apărea în fereastra cu rezultate pentru a indica că testul a fost petrecut corect ,iar dispozitivul-test funcţionează corespunzător.Dacă antigenii H.pylori nu sunt prezenţi sau sunt sub limita de detecţie a testului, doar linia de control a testului va fi vizibilă. Dacă linia de control nu este vizibilă, testul este invalid.

PRECAUȚII

1. Acest kit este destinat numai pentru diagnostic in vitro.
2. Purtați mănuși în timpul întregii proceduri.
3. Nu utilizați conținutul kit-ului după data de expirare.
4. Toate probele trebuie tratate ca potențial infecțioase.
5. Urmați procedura de laborator și orientările de securitate biologică standarde pentru manipularea și eliminarea materialului potențial infecțios.

PROCEDURA DE TESTARE

1. Aduceți toate materialele și specimenele la temperatura camerei.
2. Scoateți banda de testare din punga din folie închisă ermetic.
3. Ţineţi sticluţa cu probă vertical cu vîrful îndreptat departe de test,scoateţi virful. pipeta de transfer pentru a trage eșantionul.
4. Țineți sticluța într-o poziție verticală peste zona de testare, apoi se repartizează 3 picături (120-150 µl) de probă pe zona de testare.
5. Citiți rezultatul în 10-15 minute. O probă puternic-pozitivă poate arăta rezultate mai devreme.

Notă: Rezultatele testului după 15 minute pot să nu fie precise.

INTERPRETAREA REZULTATELOR

Pozitiv: O bandă roză distinct coloră apare pe regiunea liniei de test, pe lîngă linia roză din regiunea de control.

Negativ: Nu apare nici o linie în regiunea liniei de test. O linie roză distinctă apare pe regiunea de control

Invalid: Linia de control de lîngă linia de test nu devine vizibilă în timp de 10 minute după adăugarea probei.

Set de teste rapide QuickProfile™ pentru anticorpi HCV

UTILIZAREA PREVĂZUTĂ

QuickProfile™ HCV Ab este un imunotest ce utilizează metoda cromatografică pentru detectarea calitativă a anticorpilor împotriva virusului hepatitei C (HCV Ab) în ser uman, plasmă sau probe de sânge integral. Testul este destinat uzului profesional și ca un ajutor pentru diagnosticarea și gestionarea pacienților în legătură cu infecția cu virusul hepatitic C, precum si pentru monitorizarea primară a sângelui de la donatori voluntari.

PRINCIPIU

Testul QuickProfile™ HCV Ab utilizează un mecanism de flux lateral cromatografic într-un format de bandă sau casetă. Antigeni HCV recombinați sunt imobilizați pe Zona de testare (T) a stripului și anticorpii IgG anti-șoarece de capră sunt imobilizați la zona de control (C) pe membrana de nitroceluloză. Când se adaugă proba, aceasta migrează prin difuzie capilară și rehidratează antigenele coloidale de aur conjugate recombinate HCV (Au-Ag), uscate pe banda din fibra de sticla. Dacă sunt prezenți în probă, anticorpii HCV se vor lega cu antigene de aur conjugat și vor forma compuși. Acești compuși vor continua să migreze de-a lungul benzii până ajung la zona de testare Zona (T) unde sunt capturate de antigeni HCV, pentru a forma o linie roșie vizibilă. IgG-ul de șoarece cu aur coloidal este utilizat ca indictor pentru linia de control. O linie roșie formată la zona de control (C) indică validitatea testului.

PRECAUȚII

1. Acest kit este destinat numai pentru diagnostic in vitro.
2. Acest kit este destinat exclusiv uzului profesional.
3. Citiți cu atenție instrucțiunile înainte de efectuarea testului.
4. Acest produs nu conține materii prime umane.
5. Nu utilizați conținutul kit-ului după data de expirare.
6. Toate probele trebuie tratate ca potențial infecțioase.
7. Urmați procedura de laborator și orientările de securitate biologică standarde pentru manipularea și eliminarea materialului potențial infecțios. În cazul în care procedura de testare este finalizată, eliminați specimene doar după autoclavare la 121ºC timp de cel puțin 20 de minute. Alternativ, acestea pot fi tratate cu 0,5% hipoclorit de sodiu timp de 1-2 ore înainte de a fi eliminate.
8. Nu pipetați reactivul cu gura și nu fumați, mâncați sau beți în timpul efectuării testelor.
9. Purtați mănuși în timpul întregii proceduri.

PROCEDURA DE TESTARE

HCV Test Strip (Număr de catalog: 71027)

1. Lăsați banda de testare și proba să ajungă la temperatura camerei, dacă este necesar.
2. Deschideți punga, scoateți banda de testare și pipeta de transfer.

3. Utilizați pipeta de transfer pentru a trage proba și dispensați o picătură (circa 40µl) la zona de testare, așa cum se arată în figură, și așteptați timp de câteva secunde până când proba este complet absorbită pe zona de testare.
4. Se adaugă o picătură (circa 40µl) de tampon pentru probă la zona de testare, așa cum se arată în figură.
5. Citiți rezultatul la 20 de minute după adăugarea probei.

HCV Test card (Număr de catalog: 71030)

1. Se lasă cartela de testare și proba să ajungă la temperatura camerei, dacă este necesar.
2. Deschideți punga, scoateți test cardul și pipeta de transfer.
3. Utilizați pipeta de transfer pentru a trage proba și dispensați o picătură (circa 40µl) la zona marcată "S" și așteptați timp de câteva secunde până când proba este complet absorbită pe zona de testare.
4. Se adaugă o picătură (circa 40µl) de tampon pentru probă la zona marcată "S".
5. Citiți rezultatul la 20 de minute după adăugarea probei.

Notă:

Anumite probe pozitive pot arăta rezultate pozitive mai devreme de 20 de minute.

Rezultate obținute după 30 de minute pot fi incorecte.

INTERPRETAREA REZULTATELOR

Pozitiv: Dacă două benzi colorate sunt vizibile în termen de 20 de minute, testul este pozitiv și valabil. Rezultatul testului poate fi citit imediat ce o bandă distinctă colorată apare în zona de testare și zona de control, respectiv.

Negativ: O singură linie roșie apărută în zona de control (C), indică faptul că nu au fost depistați anticorpi HCV Ab. Cu toate acestea, acest rezultat nu exclude complet posibilitatea de infectare cu HCV.

Invalid: În cazul în care nici o bandă colorată nu apare în zona de control (C), rezultatul testului este invalid, iar testul trebuie repetat. În cazul în care aceeași situație sa întâmplat din nou, vă rugăm să opriți utilizarea acestui lot de produse și contactați furnizorul.

Set de teste rapide QuickProfile™ pentru antigeni HBs

UTILIZAREA PREVĂZUTĂ

QuickProfile™ HBsAg este un in vitro imunotest ce utilizează metoda cromatografică pentru detectarea rapidă şi calitativă a antigenelor H.pylori în masele fecale umane. Rezultatele testului au intenţia de a ajuta în diagnosticarea infecţiei cu H.pylori, de a monitoriza eficacitatea tratamentului terapeutic şi confirmarea eradicării H.pylori la pacienţii cu ulcer peptic.

PRINCIPIU

Testul QuickProfile™ HCV Ab utilizează un mecanism de imunotest tip sandwich cu anticorpi dubli. Complexe de anticorpi anti-HbsAg conjugați cu aur coloidal sunt imobilizați pe membrana de nitroceluloză. Când se adaugă proba, aceasta migrează prin difuzie capilară și rehidratează conjugatele de aur coloidal. Dacă sunt prezenți în probă, HBsAg se vor lega cu antigenii conjugați cu aur și vor forma particule. Aceste particule vor continua să migreze de-a lungul benzii până ajung la zona de testare Zona (T) unde sunt capturate de anticorpi anti-HBsAg, pentru a forma o linie roșie vizibilă. IgG-ul de șoarece cu aur coloidal este utilizat ca indictor pentru linia de control. O linie roșie formată la zona de control (C) indică validitatea testului.

PRECAUȚII

1. Acest kit este destinat numai pentru diagnostic in vitro.
2. Acest kit este destinat exclusiv uzului profesional.
3. Citiți cu atenție instrucțiunile înainte de efectuarea testului.
4. Acest produs nu conține materii prime umane.
5. Nu utilizați conținutul kit-ului după data de expirare.
6. Toate probele trebuie tratate ca potențial infecțioase.
7. Urmați procedura de laborator și orientările de securitate biologică standarde pentru manipularea și eliminarea materialului potențial infecțios. În cazul în care procedura de testare este finalizată, eliminați specimene doar după autoclavare la 121ºC timp de cel puțin 20 de minute. Alternativ, acestea pot fi tratate cu 0,5% hipoclorit de sodiu timp de 1-2 ore înainte de a fi eliminate.
8. Nu pipetați reactivul cu gura și nu fumați, mâncați sau beți în timpul efectuării testelor.
9. Purtați mănuși în timpul întregii proceduri.

PROCEDURA DE TESTARE

HBsAg Test Strip (Număr de catalog: 71003)

1. Aduceți toate materialele și specimenele la temperatura camerei.
2. Scoateți banda de testare din punga din folie închisă ermetic.
3. Marcați banda de testare cu identitatea probei scriind identificatorul pe partea de sus a benzii.
4. Se pune banda de testare pe o suprafață netedă orizontală.
5. Utilizați pipeta de transfer pentru a trage eșantionul.
6. Țineți pipeta de transfer într-o poziție verticală pe zona de testare, apoi se repartizează 2 picături (80-100 µl) de probă pe zona de testare.

7. Citiți rezultatul la 20 de minute după adăugarea probei.

HBsAb Test card (Număr de catalog: 71006)

1. Aduceți toate materialele și specimenele la temperatura camerei.
2. Scoateți test cardul din punga din folie închisă ermetic.
3. Marcați test cardul cu identitatea probei scriind identificatorul pe partea de sus.
4. Așezați test cardul pe o suprafață netedă orizontală.
5. Utilizați pipeta de transfer pentru a trage eșantionul.
6. Țineți pipeta de transfer într-o poziție verticală pe zona de testare, apoi se repartizează 2 picături (80-100 µl) de probă pe zona de testare.
7. Citiți rezultatul la 20 de minute după adăugarea probei.

Notă:

Anumite probe pozitive pot arăta rezultate pozitive mai devreme de 20 de minute.

Rezultate obținute după 30 de minute pot fi incorecte.

INTERPRETAREA REZULTATELOR

Pozitiv: Dacă două benzi colorate sunt vizibile în termen de 20 de minute, testul este pozitiv și valabil. Rezultatul testului poate fi citit imediat ce o bandă distinctă colorată apare în zona de testare și zona de control, respectiv.

Negativ: O singură linie roșie apărută în zona de control (C), și nici o bandă colorată nu apare în zona de test (T) – Rezultatul testului este negativ și valid.

Invalid: În cazul în care nici o bandă colorată nu apare în zona de control (C), rezultatul testului este invalid, iar testul trebuie repetat. În cazul în care aceeași situație sa întâmplat din nou, vă rugăm să opriți utilizarea acestui lot de produse și contactați furnizorul.