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: 2022.09.29 09:30:51 EEST
Reason: MoldSign Signature
Location: Moldova

Emergo Europe Molenstraat 15, 2513 BH The Hague, The Netherlands Telephone: +31.70.345.8570 Fax: +31.70.346.7299

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

CONFORMITY ASSESSMENT		
Device classification	**Route to compliance**	**Standards applied**
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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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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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)

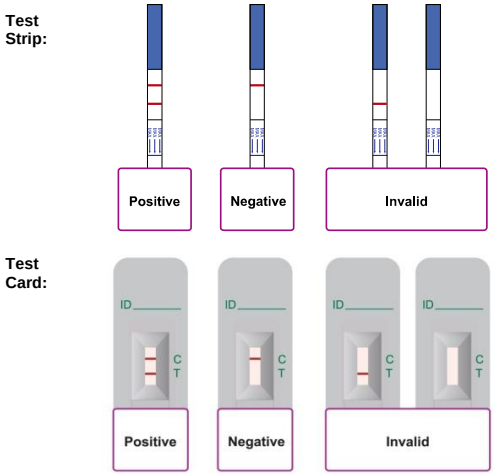
1. Bring all materials and specimens to room temperature.
2. Remove the test strip from the sealed foil pouch.
3. Label the test strip with specimen identity by writing the ID on the top label of the strip.
4. Place the test strip on a flat horizontal surface.
5. Use the transfer pipet to draw up the 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

1. Sehulster, L. et al. Immunological and biophysical alteration of Hepatitis B virus antigens by sodium hypochlorite disinfection, Appl. And Envir. Microbiol., 42:762-767, 1981.
2. U.S. Department of Health and Human Services. Biosafety in microbilogical and biomedical laboratories. HHS Publication(NIH) 88-8395. Washington:U.S. Government Printing Office, May 1988.

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.

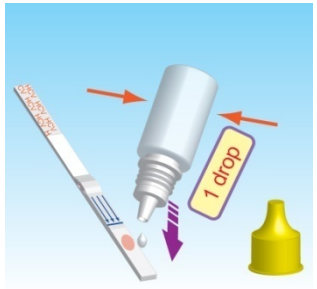
SPECIMEN COLLECTION AND PREPARATION

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

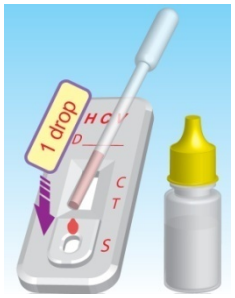
For HCV Test Strip (Catalog Number: 71027)

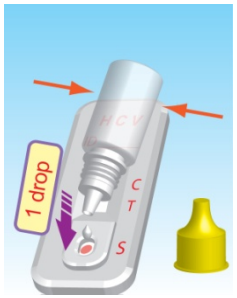
1. Allow the test strip and sample to reach room temperature if necessary.
2. Open the pouch, Take out the test strip and transfer pipet.
3. Using the transfer pipet to draw up the sample, dispense one drop (approx 40µl) specimen to the sample pad as shown in the illustration, and wait for a few seconds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

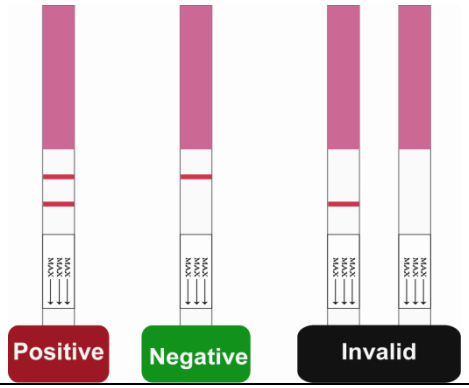
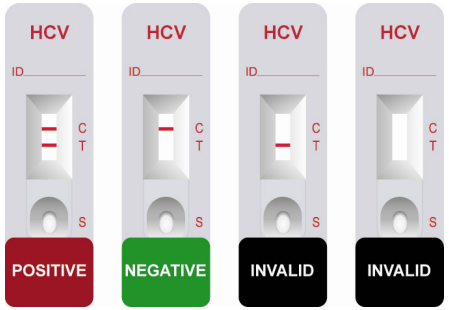
1. Allow the test card and sample to reach room temperature if necessary.
2. Open the pouch, Take out the test card and transfer pipet..
3. Using the transfer pipet to draw up the sample, dispense one drop (approximately 40µl) of specimen to the sample well marked as "**S**" and wait for a few seconds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

1. Post transfusion hepatitis. In: Moore SB, ed. Transfusion-Transmitted Viral Diseases. Alington, VA. Am. Assoc. Blood Banks, pp. 53-38.
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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LumiQuick
DIAGNOSTICS, INC.

QuickProfile™ H. PYLORI ANTIBODY TEST

REF	71024
REF	71046
REF	71064

A Rapid qualitative Immunochromatographic test for the detection of antibodies against H. Pylori in human Whole Blood, Serum or plasma

INTENDED USE

QuickProfile™ H. Pylori Antibody Test is a rapid immune-chromatographic assay for the detection of antibodies to H. pylori in human whole blood, serum or plasma. The assay is to provide an aid in diagnosis of H. pylori infection.

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, infected 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* infection develops 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 Antibody Test is an immune-chromatographic assay that uses double antigen sandwich technology to detect the presence of *H. pylori* antibody in human blood specimens. The test is simple and easy to perform and the test results can be visually interpreted within 10 minutes

TEST PRINCIPLE

QuickProfile™ H. Pylori Antibody Test employs chromatographic lateral flow test device in a cassette or strip format. Colloidal gold conjugated H. pylori antigens (Au-Ag) are dry-immobilized at the end of nitrocellulose membrane strip. H. Pylori antigens are bond at the Test Zone (T) When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate. If anti-H. pylori antibodies present in sample, Antibodies will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by H. pylori antigens generating a visible red line. If there are no anti-H. Pylori antibodies in sample, no red line is formed in the Test Zone (T). A built-in control line will always appear in the Control Zone (C) when the test has performed properly, regardless of the presence or absence of anti-H. pylori antibodies in the specimen.

REAGENTS AND MATERIALS SUPPLIED

Each kit contains:
1. QuickProfile™ H. Pylori Test in foil pouch
2. Product insert

MATERIALS NOT PROVIDED

1. Sepcimen collection container
2. Timer

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 4-30°C for the duration of the shelf life as indicated on the 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 complete, dispose 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 no smoking or eating while performing assays.
9. Wear gloves during the whole procedure.

SPECIMEN COLLECTION AND PREPARATION

1. No prior special preparation of the patient is required before sample collection by approved techniques.
2. Fresh serum / plasma is preferable. Serum / plasma may be stored at 2-8°C up to 3 days in case of delay in testing. For long-term storage, freeze the specimen at -20°C for 3 months or -70°C for longer periods.
3. The test works best on fresh whole blood samples. If testing cannot be done immediately, Blood samples collected with a suitable anticoagulant such as EDTA or Heparin should be stored at 2-8ºC up to 3 days. Blood samples should not be frozen.
4. Repeated freezing and thawing of the specimen should be avoided.
5. Do not use haemolysed, clotted, contaminated, lipamic and viscous/turbid specimen.
6. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
7. Do not heat inactivate the sample.
8. Shipment of samples should comply with local regulations for transport of etiologic agents.

PROCEDURE

For Test Strip (71064):

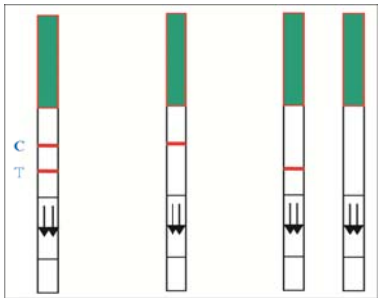
1. Allow the strip and sample to reach room temperature if necessary.
2. Open the pouch, dip the strip into the specimen with the arrow marked end toward the sample until the sample move to the membrane or pipette 80-100 µl (Two drops) of serum or plasma to the arrow marked end of the strip.
3. Place the strip on flat surface and read the results at 10 minutes. A strong positive sample may show result earlier.

For Test Card (71024 or 71046)

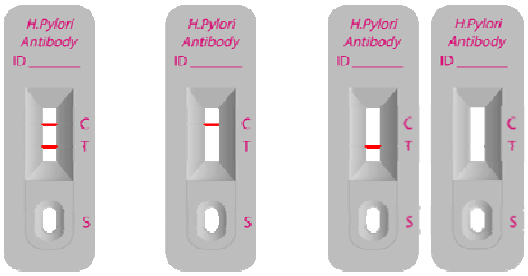
1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the Card. Once opened, the test card must be used immediately.
3. Label the test card with patients identity.
4. Apply 3 drops (120-150 µL) of serum, plasma or whole blood to the sample well marked as "**S**'.
5. At the end of 10 minutes read the results. A strong positive sample may show result earlier.

INTERPRETATION OF RESULTS

Test strip



Test Card



Positive Negative Invalid

1. *Negative*
   Only control line appears.
2. *Positive*
   Both control line and the test line appear. It indicates the antibodies to H. pylori have been detected.
3. *Invalid Result*
   If after 10 minutes no line is visible within the Control Zone, the result is invalid. The test should be repeated with a new test card.

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 which is not provided with this test kit may be commercially available.

LIMITATIONS

1. The test is for qualitative detection of anti-H. pylori antibodies in human serum, plasma or blood sample and dose not indicate the quantity of the antibodies.
2. The test is for *in vitro* diagnostic use only.
3. 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.

PERFORMANCE CHARACETERISTICS

1. **Accuracy**

A panel of 30 positive and 61 negative patient sera was tested with a reference ELISA test. The results are summarized in the following table. The agreement is 100%.

	ELISA H. Pylori Antibody Test		
QuickProfile™ ***H. Pylori Ab Test***		Positive	Negative
	Positive	30	2
	Negative	0	65
	Agreement	100%	97%

2**. Interference**

No interference was found with bilirubin (10 mg/dL), Cholesterol (800 mg/dL), hemoglobin (250 mg/dL) or triglycerides (500 mg/dL) on the sensitivity and specificity of the test.

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IVD

4°C 30°C

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