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: 2022.03.21 14:06:03 EET
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

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

Tel: 408-855-0061
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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

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COMPANY REPRESENTATIVE: Jeff Wang

TITLE: Quality Systems Manager **SIGNATURE:**

DATE: 28/04/2017

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.

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

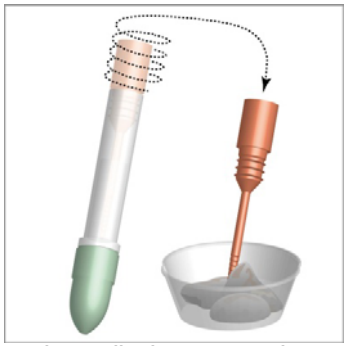
1. For in-vitro diagnostic use only.
2. Do not use product beyond the expiration date.
3. Handle all specimens as potentially infectious.

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

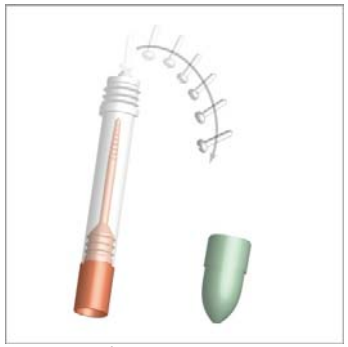
Specimen collection Steps 5 and 6

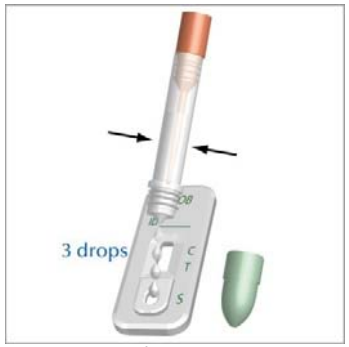
SPECIMEN STABILITY
The sample can be stored at room temperature (8 - 30°C) up to seven days if not immediately tested. If the condition allowed, the sample can also be refrigerated (2 – 8°C) for better storage.

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



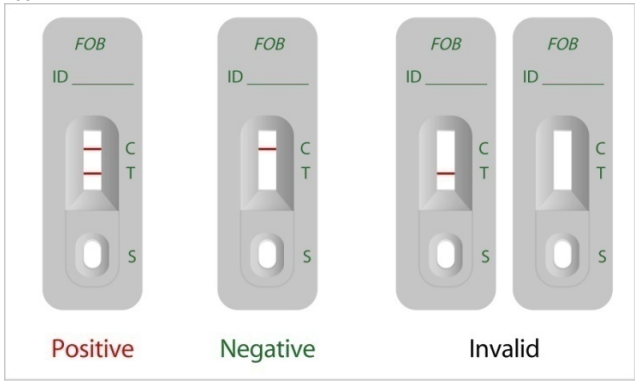
Assay Procedure Step 4

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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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]

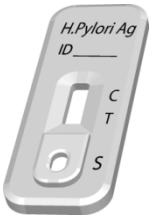
QuickProfile™ H. pylori Antigen Test is an immune-chromatographic assay that uses antibody- coated colloidal gold to detect the presence of *H. pylori* antigens in stool specimens. The test detects directly antigens in specimens for an active infection. The test is simple and easy to perform and the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

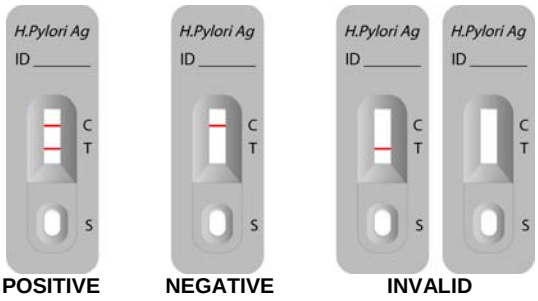
   Test results after 15 minutes may not be accurate.

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.
5. Talley NJ, Newell DG, Ormand JE, et al. Serodiagnosis of *Helicobacter pylori*: Comparison of enzyme-linked immunosorbent assays. *J. Clin Microbiol*. 1991;29:1635-1639.
6. Cutler AF. Testing for *Helicobacter pylori* in clinical practice. *Am J. Med*. 1996;100:35S-41S.
7. Klein PD, Malaty HM, Martin RF, et al. Noninvasive detection of *Helicobacter pylori* infection in clinical practice: the ^{13}C urea breath test. *Am J. Gastroenterol*. 1996;91:690-694.
8. National Committee for Clinical Laboratory Standards. Internal quality control: Principles and definitions; Approval Guideline, NCCLS document C24-A (NCCLS, 771 East Lancaster Ave, Vallanova, PA 19085, 1991).
9. Marshall BJ. *JAMA*. 1995;274:1064-1066
10. Breuer T, Malaty HM, Graham DY. The epidermiology of H. pylori-associated gastroduodenal diseases. In: Ernst PB, Michetti P, Smith PD, eds. The Immunobiology of H. pylori: From Pathogenesis to Prevention. Philadephia. Lippincott-Raven, 1997:1-14.
11. Graham DY, Malaty HM, Evans DG, Evans, Jr. DJ, Klein PD, and Adam E. Epidermiology of *Helicobacter pylori* in a asymptomatic population in the United States. Effect of age, race, and socioeconomic status. *Gastroenterology*, 1991;100:1495-1501.
12. Anand BS, Raed AK, Malaty HM, et al. Low point prevalence of peptic ulcer in normal individual with *Helicobacter pylori* infection. *Am J Gastroenterol*. 1996,91:1112-1115.
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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