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 Gangan Dumitru
Date: 2021.08.05 14:17:26 EEST
Reason: MoldSign Signature
Location: Moldova

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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

Set de teste rapide QuickProfile™ pentru Sânge Fecal Ocult

UTILIZAREA PREVĂZUTĂ

QuickProfile™ FOB este un test calitativ ce detectează homoglobină umană în probe de mase fecale umane. Este un test in vitro cu citire vizuală. Rezultatele testului au intenţia de a ajuta în diagnosticarea de sângerare gastrointestinală.

PRINCIPIU

Testul QuickProfile™ FOB este compus din două unități, tub de colectare a probelor fecale și test cardul. Proba fecală este colectată în tubul cu conținut de bufer de extracție, iar apoi este adăugat pe test card. Când proba este adăugată pe test, această se mișcă pe strip și mobilizează conjugatul de anticorpi homoglobin anti-h cu aur căptușit pe test strip.Mixtura se mișcă prin acțiune capilară și reacționează cu anticorpii hemoglobin anti-h de pe regiunea de testare. Dacă hemoglobina este prezentă în probă în cantități de 50 ng/mL sau mai mari, rezultatul este formarea unei benzi colorate roșu pe zona de testare. În caz contrar linia roșie nu va apărea. 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.

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.

PREGĂTIREA PACIENTULUI

1. Proba nu trebuie colectată în timpul ciclului menstrual și până la 3 zile după, sau dacă pacientul suferă de hemoroizi sângeroși sau dacă are sânge în urină.
2. Alcool, aspirină și alte medicamente luate în exces, pot provoca iritări gastrointestinale rezultâng în sângerare ocultă. Consumul substanțelor date trebuie sistat cu cel puțin 48 ore înainte de colectarea probei.
3. Restricționări dietetice nu sunt necesare.

COLECTAREA PROBEI CU TUBUL DE TIP I

1. Probele de mase fecale pot fi colectate în orice oră a zilei.
2. Colectați o cantitate mică de probă într-un recipient curat și uscat.
3. Scoateți capacul din capătul roșu al tubului și scoateți bețișorul de aplicare.
4. Introduceți bețișorul în probă în mai multe locuri.
5. Introduceți bețișorul înapoi în tub și înșurubați.
6. Scuturați tubul viguros imp de 5 secunde pentru a dispersa proba în buferul de colectare.

Specimen collection Steps 3 and 4

Specimen collection Steps 5 and 6

COLECTAREA PROBEI CU TUBUL DE TIP II

1. Probele de mase fecale pot fi colectate în orice oră a zilei.
2. Colectați o cantitate mică de probă într-un recipient curat și uscat.
3. Scoateți capacul din capătul roșu al tubului și scoateți bețișorul de aplicare.
4. Introduceți bețișorul în probă în mai multe locuri.
5. Introduceți bețișorul înapoi în tub și înșurubați.
6. Scuturați tubul viguros imp de 5 secunde pentru a dispersa proba în buferul de colectare.

Specimen collection Steps 3 and 4

Specimen collection Steps 5 and 6

CONTROLUL CALITĂȚII

1. Se recomandă utilizarea unui control pozitiv, cu valoare de hemoglobină între 50-200 ng/mL, și un control negativ cu valoarea 0 ng/mL. Materialul de control nu este disponibil ca parte a setului, dar poate fi ușor obținut comercial.
2. Banda de control de pe strip conține reagent și reprezintă un cotrol procedurii de testare. Această va apărea colorată pe strip dacă testarea a fost efectuată cu succes și indică reactivitatea reagenților.

PROCEDURA DE TESTARE

1. Aduceți toate materialele și specimenele la temperatura camerei.
2. Scoateți banda de testare din punga din folie închisă ermetic.
3. 3.1 Dacă se folosește tubul de tip I, scoateți capacul verde de protecție. Ținând tubul vertical, rupeți vârful din plastic.
   3.2 Dacă se folosețte tubul de tip II, țineți tubul vertical și rupeți vârful din plastic.

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 3-10 minute.

Notă: Rezultatele testului după 10 minute pot să nu fie precise.

Assay Procedure Step 3.1

Assay Procedure Step 4

Assay Procedure Step 3.2

Assay Procedure Step 4

INTERPRETAREA REZULTATELOR

Pozitiv: O bandă roză distinct coloră apare pe regiunea liniei de test, pe lîngă linia roză din regiunea de control. **Notă**: La probele cu nivel scăzut de hemoglobină, reacția de colorare poate dura mai mult de 10 minute.

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.

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

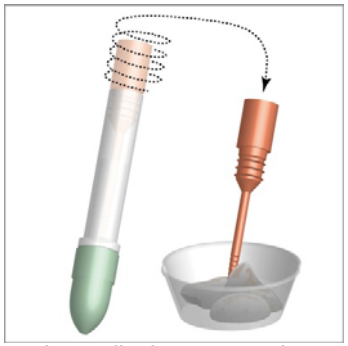
1. For in-vitro diagnostic use only.
2. Do not use product beyond the expiration date.
3. Handle all specimens as potentially infectious.

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

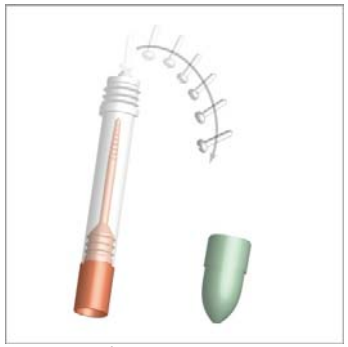
Specimen collection Steps 5 and 6

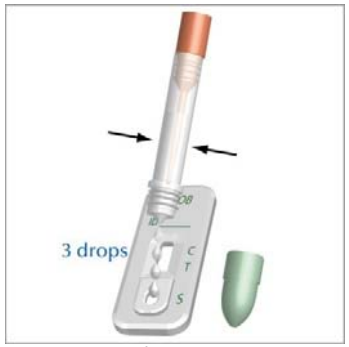
SPECIMEN STABILITY
The sample can be stored at room temperature (8 - 30°C) up to seven days if not immediately tested. If the condition allowed, the sample can also be refrigerated (2 – 8°C) for better storage.

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



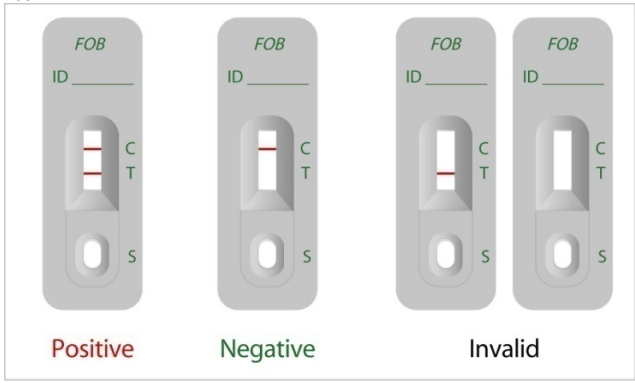
Assay Procedure Step 4

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

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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).
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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.™