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: 2022.03.04 16:44:24 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**
Cardiac Marker Test Devices	
QuickProfile Troponin I Serum Test Card	75001
QuickProfile Troponin I Whole Blood Test Card	75002
QuickProfile Cardiac Panel Serum Test Card	75003
QuickProfile Cardiac Panel Whole Blood Test Card	75004
QuickProfile Myoglobin Serum Test card	75005
QuickProfile Myoglobin Whole Blood Test Card	75006
QuickProfile CK-MB Serum Test Card	75007
QuickProfile CK-MB Whole Blood Test Card	75008
QuickProfile Troponin I Strip	75009
QuickProfile CK-MB Strip	75010
QuickProfile Myoglobin Strip	75011

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

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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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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LumiQuick

DIAGNOSTICS, INC.

Quick Profile™ Cardiac Panel Test
Serum and Plasma

FOR THE QUALITATIVE ASSESSMENT OF CARDIAC TROPONIN I, CK-MB AND MYOGLOBIN IN HUMAN SERUM OR PLASMA

Catalog Number: 75003

For in vitro Diagnostic Use

INTENDED USE

Quick Profile™ Cardiac Panel test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of cardiac troponin I (cTnI), CK-MB and Myoglobin in human serum, plasma or whole blood specimens as an aid in the diagnosis of myocardial infarction.

SUMMARY AND EXPLANATION

Cardiac troponin I (cTnI) is a cardiac muscle protein with a molecular weight of 22.5 kilodaltons. Together with troponin T (TnT) and troponin C (TnC), TnI forms a troponin complex in heart to play a fundamental role in the transmission of intracellular calcium signal actin-myosin interaction. The human cTnI has an additional amino acid residues on its N-terminal that are not exist on the skeletal forms thus making cTnI a specific marker for indicating cardiac infarction. cTnI is released rapidly into blood after the onset of acute myocardial infarction (AMI). Its release pattern is similar to CK-MB (4-6 hours after the onset of AMI). However, CK-MB level returns to normal after 36-48 hours, while levels of cTnI remains elevated for up to 6-10 days. The level of cTnI is very low in normal healthy people, and not detected in patients with skeletal muscle injury. Therefore, cTnI is a specific marker for diagnosis of acute myocardial infarction.

Creatine kinase is a dimer occurring in various in three isoenzymic forms, depending on the particular combination of its non-identical subunits:BB(brain type);MM(skeletal type); and MB(hybrid type). Creatine kinase-MB isoenzyme is released into circulation later than myoglubin, reaching abnormal levels within 4 to 6 hours after onset of symptoms,it reaches its highest level with a typical range of 39-185 ng/mL after about 18 to 24 hours,and returns to normal in about 2 to 3 days.CK-MB is widely recognized as the traditional marker for the diagnosis of AMI.

Myoglobin is a low molecular weight, cytoplasmic serum protein. Due to its low molecular weight, myoglobin is released more rapidly when muscle cells are damaged than other markers. Serum concentration of myoglobin increases above the normal range as early as 1 hour after myocardial infarction, and peak in approximately 4 to 8 hours after onset. Therefore, myoglobin is better suited for the early diagnosis of AMI.

Quick Profile™ Cardiac Panel test is a sandwich immunoassay. When serum sample is added to sample pad, it moves through the conjugate pad and mobilizes gold antibody conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-cardiac marker antibodies that is coated on the test region. If cardiac markers are present at levels of cut-off level or greater, the result is the formation of a colored band in the test region. If there are no cardiac markers in the sample, the area will remain colorless. The sample continues to move to the control area and forms a pink to purple color, indicating the test is working and the result is valid.

Below are the cut-off concentrations for each cardiac marker using in the test.

Troponin I	1.0 ng/mL
CK-MB	7.0 ng/mL
Myoglobin	100 ng/mL

MATERIAL PROVIDED

1. Quick Profile™ Cardiac Panel Test device

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. Micropipetter (100-1000 μL range) and pipet tips
4. Timer or clock

STORAGE

Store the test device at 4 to 30°C. Do Not Freeze.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. The serum or plasma 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 affecting the test results.

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 are not provided with this test kit are commercially available.

PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Place the transfer pipette in the specimen and depress the bulb to withdraw a sample.
4. Hold the pipette in a vertical position over the sample well of the test card and deliver 3 drops (120-150 μl) of sample to each sample well well.
   Note: Please deliver sample drop by drop to ensure the best performance
5. Read the result at 15 minutes.

INTERPRETATION OF RESULTS

Positive:

If two colored bands are visible on any strip of the device within 15 minutes, the test result is positive and valid. The test result can be read as soon as a distinct colored band appears in the test area.

Note: Specimens containing very low levels of cardiac markers may develop two color bands over 15 minutes.

Negative:

If test area has no color band and the control area displays a colored band, the result is negative and valid.

Invalid result:

If a colored band does not form in the control region of any strip, the test result is invalid. The sample must be re-tested, using a new test device.

If after 15 minutes, you see one of the following results. It may imply the indicated syndrome.

a) MYG-positive/CKMB-positive/TnI-positive
(MYO ≥ 100 ng/mL, CK-MB ≥ 7.0 ng/mL, Tn I ≥ 1.0ng/mL)
Myocardial cell necrosis within the past 12 hours.

b) MYG-positive/CKMB-positive/TnI-negative
(MYO ≥ 100 ng/mL, CK-MB ≥ 7.0 ng/mL, Tn I < 1.0ng/mL)
Early muscle or cardiac injury. Serial Troponin I testing is suggested in 4 & 8 hrs to rule in acute coronary syndrome

c) MYG-negative/CKMB-positive/TnI-positive
(MYO < l00 ng/mL, CK-MB ≥ 7.0 ng/mL, Tn I ≥ 1.0ng/mL)
Acute myocardial infarction post 12 hours from the onset of early symptoms

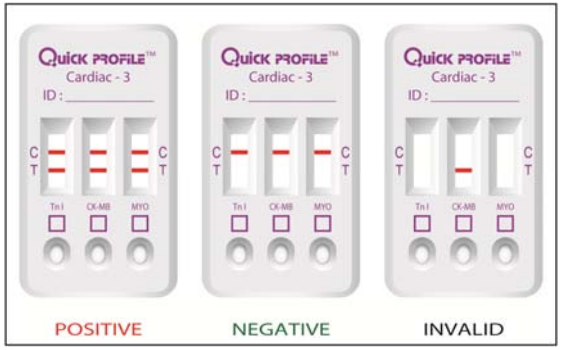
d) MYG-negative/CKMB-positive/TnI-negative
(MYO <.100 ng/mL, CK-MB ≥ 7.0 ng/mL, Tn I < 1.0ng/mL)
Early muscle or cardiac injury. Serial Troponin I testing is suggested in 4 & 8 hrs to rule in acute coronary syndrome.

e) MYG-negative/CKMB-negative/TnI-positive
(MYO < l00 ng/mL, CK-MB < 7.0 ng/mL, Tn I ≥ 1.0ng/mL)
Acute myocardial infarction post 24-96 hours

f) MYG-positive/CKMB-negative/TnI-negative
(MYO ≥ l00 ng/mL, CK-MB < 7.0 ng/mL, Tn I < 1.0ng/mL)
Early muscle or cardiac injury. Serial Troponin I testing is suggested in 4 & 8 hrs to rule in acute coronary syndrome. (MYO ≥ l00 ng/mL, CK-MB < 7.0 ng/mL, Tn I < 1.0ng/mL).

g) MYG-positive/CKMB-negative/TnI-positive
(MYO ≥ l00 ng/mL, CK-MB < 7.0 ng/mL, Tn I ≥ 1.0ng/mL).
A very possible myocardial cell necrosis

h) MYG-negative/CKMB-negative/TnI-negative
(MYO < l00 ng/mL CK-MB < 7.0 ng/mL, Tn I < 1.0 ng/mL)
Acute myocardial infarction may not happen. If the cardiac injury is suspected, retest in 2 - 4 hours.



LIMITATIONS OF THE PROCEDURE

1. The test result should be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnose AMI. A negative result obtained from a patient whose sample was taken at 2-20 hours after the onset of chest pain may help in ruling out AMI. A positive result from a patient suspected of AMI may be used as a rule-in diagnosis and requires further confirmation. Serial sampling of patients suspected of AMI is also recommended due to the delay between the onset of symptoms and the release of the cardiac markers in to the bloodstream.
2. A number of conditions, other than myocardiac infarction, including polymyositis, dermatomyositis, systemic lupus erythematosus, shock, severe renal failure, or muscle damage caused by trauma, ischemia and inflammation, can cause elevated levels of myoglobin. These conditions should be considered with appropriate clinical evidence. Recent cardioversion or an anginal episode may increase myoglobin level. Testing 12 hours or later after onset of myocardial infarction can produce misleading results, because serum levels may already have returned to normal range.
3. Quick Profile™ Cardiac Panel test only provides qualitative result. A quantitative assay method must be used to determine the concentrations of each marker. Because of the nature of qualitative visual assay, samples contained the analyte less than the claimed sensitivity level may show positive results.
4. 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.

EXPECTED VALUES

Quick Profile™ Cardiac Panel designed to yield a positive result for the concentrations of cTnI of 1.0 ng/mL or greater, CK-MB at 7 ng/mL or greater and myoglobin at 100 ng/mL or greater. The time required for blood cTnI level to reach the upper limit of normal has been found to be 4-6 hours after the onset of symptoms. cTnI level reaches the maximum concentration after 12-24 hours of the onset, and then remains elevated for 6-10 days in some cases. Therefore, a negative result within the first hours of the onset of symptoms does not rule out AMI with certainty. If suspected, repeat the test at appropriate intervals.

The time required for blood CK-MB level to reach the upper limit of normal has been found to be 4-6 hours after the onset of symptoms. CK-MBI level reaches the maximum concentration after 18-24 hours of the onset, and then remains elevated for 2-3 days in some cases. Therefore, a negative result within the first 4 hours of the onset of symptoms does not rule out AMI with certainty. If suspected, repeat the test at appropriate intervals.

Normal human serum may contain myoglobin ranging from 5 to 70 ng/mL. After 1 hour of the onset of myocardial infarction, serum myoglobin level can elevate to 200 ng/mL or even higher. During the peak hour, myoglobin level can be as high as 900 ng/mL. The level of myoglobin usually returns to normal 12 hours after the onset of the myocardial infarction. Elevated myoglobin level has also been observed in patients with other diseases as mentioned in LIMITATIONS OF THE PROCEDURE.

PERFORMANCE CHARACTERISTICS

Sensitivity:

Quick Profile™ Cardiac Panel test has the analytical sensitivity of 1.0 ng/mL for Troponin I, 7.0 ng/ml for CK-MB and 100 ng/ml for myoglobin.

The clinical sensitivity and specificity based on the clinical samples are summarized as below.

1. Troponin I

	Troponin I		
	Negative (0 ng/mL)	Tn I (0.08 – 0.92 ng/mL)	Tn I (≥ 1.0 ng/mL)
Number of specimen	51	16	64
Negative	50	8	1
Positive	1	8	63
Specificity/Sensitivity	Specificity 98%	Sensitivity 50%	Sensitivity 98.4%

2. CK-MB

	CK-MB		
	Negative (0 ng/mL)	CK-MB (1.0 – 6.0 ng/mL)	CK-MB (≥ 7.0 ng/mL)
Number of specimen	47	13	48
Negative	47	5	3
Positive	0	8	45
Specificity/Sensitivity	Specificity 100%	Sensitivity 61.5%	Sensitivity 93.8%

3. Myoglobin

	Myoglobin		
	Negative (0 ng/mL)	Myo (11.6 – 80.6 ng/mL)	Myo (≥ 90 ng/mL)
Number of specimen	47	9	44
Negative	47	5	1
Positive	0	4	43
Specificity/Sensitivity	Specificity 100%	Sensitivity 44.4%	Sensitivity 97.7%

Accuracy

Quick Profile™ Cardiac Panel test has been evaluated in the clinical site and compare with the approved predicate kit. The results show that QuickProfile™ Cardiac Panel Test has the equivalent performance as the predicate product. The results are summarized as below.

1. Troponin I

Two hundreds and six (206) samples were tested. Among them, sixty two (62) samples were tested positive by predicate kit and one hundred and forty four (144) were tested negative by predicate kit.

		Predicate Kit		Total
		Positive	Negative	
Quick Proifile™ Cardiac Panel	Positive	62	0	62
	Negative	0	144	144
Total		62	144	206

Agreement of Positive = 62/62 = 100%
Agreement of Negative = 144/144 = 100%
Total Agreement = (62+144) / (62+144) = 100%

2. CK-MB

Two hundred and thirteen (213) samples were tested. Among them, sixty six (66) samples were tested positive by predicate kit and one hundred and forty seven (147) were tested negative by predicate kit.

		Predicate Kit		Total
		Positive	Negative	
Quick Proifile™ Cardiac Panel	Positive	66	0	66
	Negative	1	146	147
Total		67	146	213

Agreement of Positive = 66/66 = 100%
Agreement of Negative = 146/147 = 99.3%
Total Agreement = (66+146)/213 = 99.5%

3. Myoglobin

Two hundred and five (205) samples were tested. Among them, sixty four (64) samples were tested positive by predicate kit and one hundred and forty one (141) were tested negative by predicate kit.

		Predicate Kit		Total
		Positive	Negative	
Quick Proifile™ Cardiac Panel	Positive	64	0	64
	Negative	1	140	141

Total	65	140	205

Agreement of Positive = 64/64 = 100%
Agreement of Negative = 140/141 = 99.3%
Total Agreement = (64+140)/205 = 99.5%

Interference testing:
The following substances were added to cardiac marker negative and cut-off level controls. No interference was found with any of the substances at the following concentrations:

Bilirubin	10 mg/dL
Cholesterol	800 mg/dL
Hemoglobin	250 mg/dL
Triglyceride	1250 mg/dL

REFERENCES

1. Adams JE, et al., Circulation, Vol. 88, 101-106 (1993)
2. Adams JE, et al., N. Eng. J. Med. Vol. 330, 670-674(1994)
3. Bodor GS, et al., Clin. Chem. Vol. 41, 1710-1715 (1995)
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5. Tucker JF, et al., Academic Emerg. Med. Vol. 4, 13-21(1997)
6. Larue C. et al., Clin Chem. Vol. 39: 972 (1993)
7. Apple FS, et al.,Clin. Chem. Vol. 41: 95 (1995)
8. Brogan GX, et al., Ann. Emerg. Med. 27: 22-28 (1996)

IVD

4°C 30°C

EC REP

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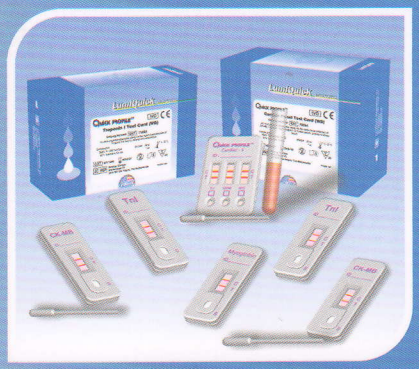
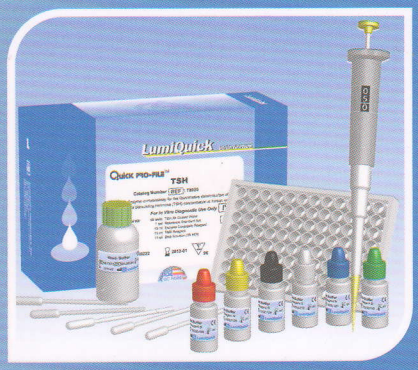
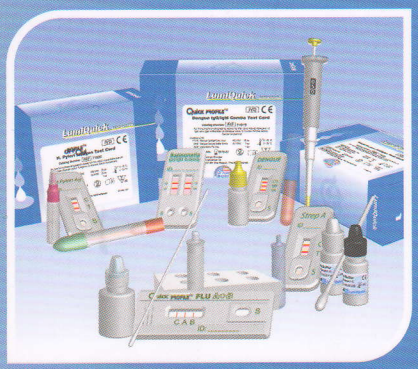


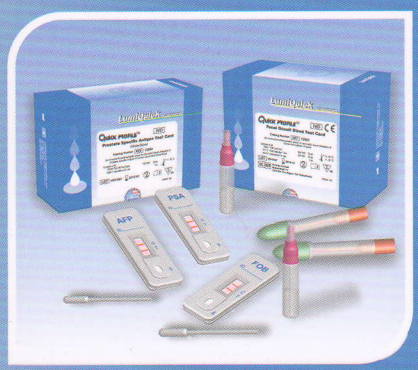
Cardiac Markers



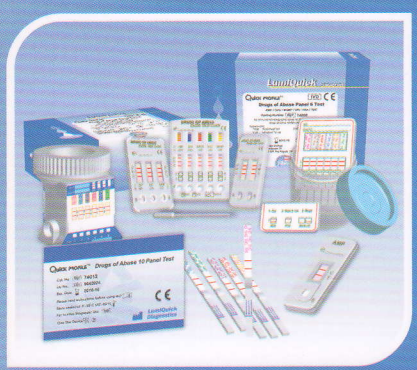
ELISA & PCR



Infectious Diseases



Cancer Markers



Drugs of Abuse

LumiQuick

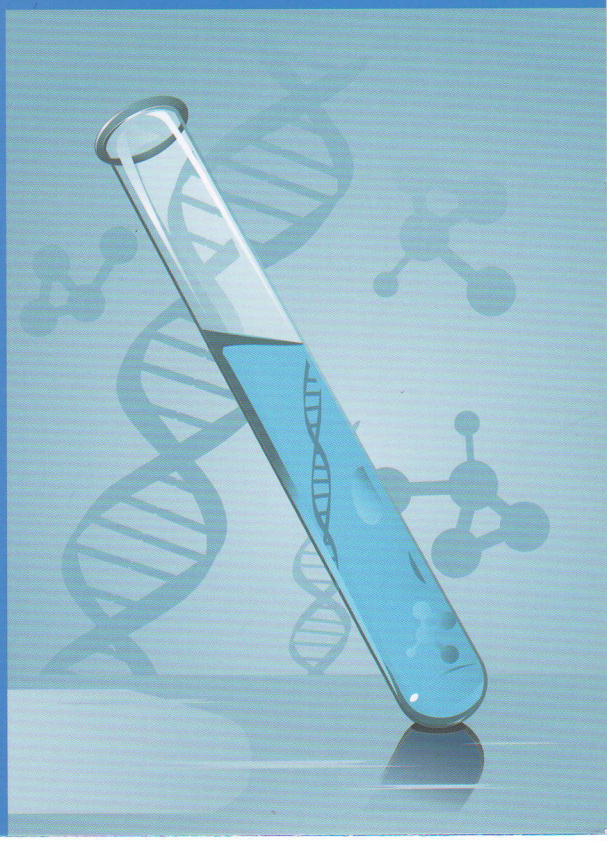
DIAGNOSTICS, INC.

In Vitro Diagnostic Devices

CATALOG

www.LumiQuick.com

www.youtube.com/lumiquickinc



LumiQuick
DIAGNOSTICS, INC.

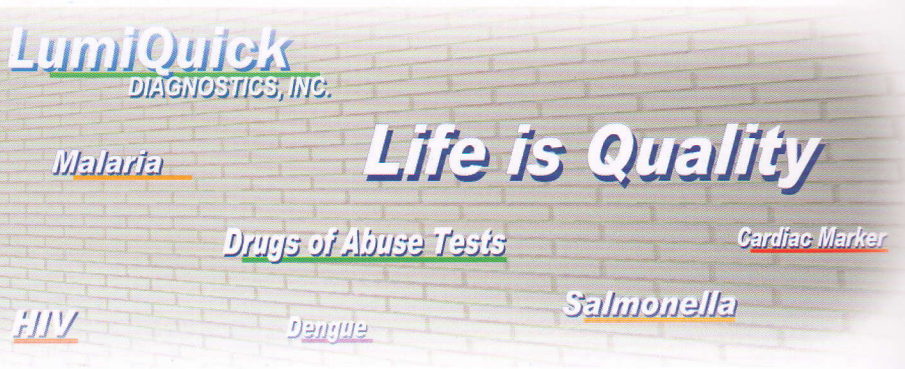
ISO 13485
ISO9001
cGMP
FDA
CE

Company Introduction

LumiQuick Diagnostics Inc., located in the heart of Silicon Valley, California, USA, develops, manufactures and markets high quality point of care tests and other immunoassay kits for the world-wide in-vitro diagnostic market. Through years of continuous and diligent efforts, we are proud to offer extensive product lines of rapid tests, ELISA, CLIA, Real Time PCR and reagent components. These product lines provide the immunoassays in various formats to detect infectious diseases, cardiac markers, cancer markers, drugs of abuse, fertility hormones and other disease markers.

Our mission is to provide the high quality products with affordable cost to help people around the world to fight human diseases and illicit substance abuse. We are committed to providing exceptional quality, customer service and cost saving to every customer.

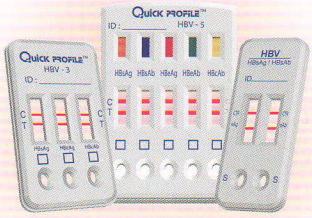
We appreciate very much your interests in our products and look forward to be your partner to fight the disease and improve human health.



Human Immunodeficiency Virus (HIV)

Cat. No.	Product Name	No. Per Kit
71001	HIV I&II Test Strip	50
71002	HIV I&II Test Card	25
71068	HIV I&II Tri-line Test Card	25

Hepatitis B Virus (HBV)



Cat. No.	Product Name	No. Per Kit
71003	HBsAg Test Strip	50
71004	HBsAg Test Card	25
71005	HBsAb Test Strip	50
71006	HBsAb Test Card	25
71007	HBcAb Test Strip	50
71008	HBcAb Test Card	25
71009	HBeAg Test Strip	50
71010	HBeAg Test Card	25
71011	HBeAb Test Strip	50
71012	HBeAb Test Card	25
71013-1	HBV-3 Panel Test Card (HBsAg/HBeAg/HBcAb)	25
71013-2	HBV-3 Panel Test Card (HBsAg/HBsAb/HBcAb)	25
71014	HBV-5 Panel Test Card (HBsAg/HBsAb/HBcAb/HBeAg/HBeAb)	25
71069-1	HBV-2 Panel Test Card (HBsAg/HBsAb)	25
	*Customized combination of Panel Test Cards are available.	

Hepatitis C Virus (HCV)

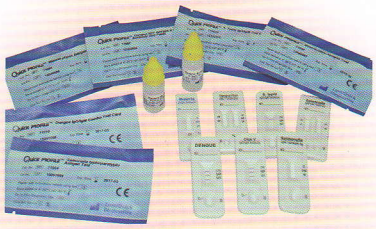
Cat. No.	Product Name	No. Per Kit
71027	HCV Antibody Test Strip	50
71030	HCV Antibody Test Card	25

Sexually Transmitted Diseases (STD)

Cat. No.	Product Name	No. Per Kit
71015	Syphilis Antibody Test Strip	50
71016	Syphilis Antibody Test Card	25
71045	Chlamydia Test Card	25

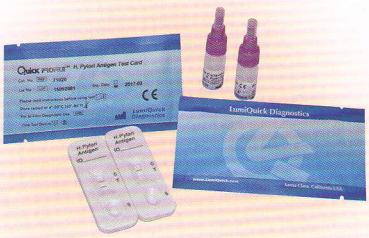
QuickProfile™ Infectious Disease Rapid Test

Tropical and Hemorrhagic Fever Diseases



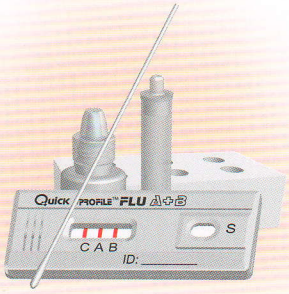
Cat. No.	Product Name	No. Per Kit
71019	Dengue IgG/IgM Combo Test Card	25
71066	Dengue NS1 Antigen Test Card	25
71087	Dengue IgG/IgM & NS1 Duo Test Card	25
71028	S. typhi Antigen Test Card	25
71054	S. typhi / paratyphi Antigen Test Card	25
71055	S. typhi IgG/IgM Duo Test Card	25
71055B	S. typhi IgG/IgM Combo Test Card	25
71049	Malaria pf Antigen Test Card	25
71050	Malaria pf/pv Antigen Test Card	25
71053	Malaria pan Antigen Test Card	25
71063	Malaria pf/pan Antigen Test Card	25
71017	Rickettsia IgG/IgM Combo Test Card	25
71018	Hantavirus IgG/IgM Combo Test Card	25
71031	Chikungunya IgG/IgM Combo Test Card	25
71078	Chagas Antibody Test Card	25

Gastro-Intestinal Diseases



Cat. No.	Product Name	No. Per Kit
71020	H. pylori Stool Antigen Test Card	25
71024	H. pylori Antibody Test Card	25
71029	Rotavirus Stool Antigen Test Card	25
71032	Adenovirus Stool Antigen Test Card	25
71033	Adeno/Rota Virus Stool Antigen Combo Test Card	25

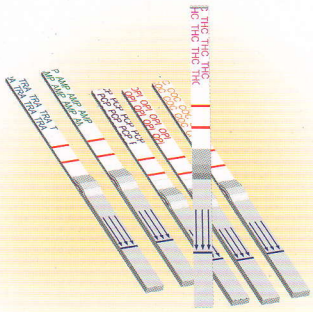
Respiratory Diseases

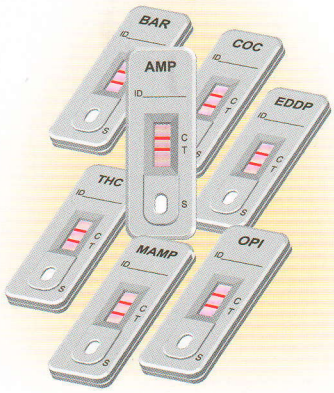


Cat. No.	Product Name	No. Per Kit
71034	Legionella Pneumonia Urinary Antigen Test Card	25
71048	Strep A Test Card	25
71062	Tuberculosis Antibody Test Card	25
71065	Influenza A (Flu A) Test Card	25
71067	Influenza A&B (Flu A&B) Combo Test Card	25

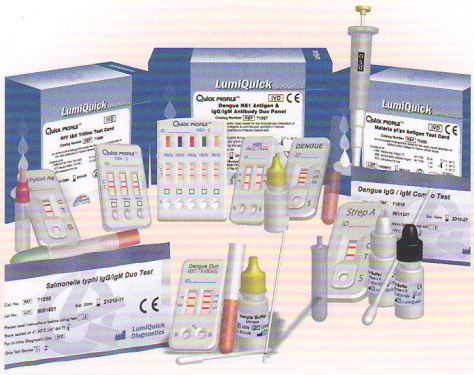
QuickProfile™ Drugs of Abuse Rapid Test

Single Test Device



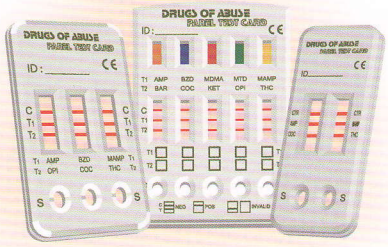


Cat. No.	Product Name	No. Per Kit
74001	Saliva Alcohol Test Strip	50
74049	Urine Alcohol Test Strip	50
74003 / 74002	Tramadol Test strip / Card	50 / 25
74013 / 74014	Amphetamine Test Strip / Card	50 / 25
74015 / 74016	Barbiturate Test Strip / Card	50 / 25
74017 / 74018	Benzodiazepine Test Strip / Card	50 / 25
74019 / 74020	Cocaine Test Strip / Card	50 / 25
74021 / 74022	EDDP Test Strip / Card	50 / 25
74023 / 74024	MDMA (Ecstasy) Test Strip / Card	50 / 25
74025 / 74026	Methadone Test Strip / Card	50 / 25
74027 / 74028	Methamphetamine Test Strip / Card	50 / 25
74029 / 74030	Opiate Test Strip / Card (300 ng/ml)	50 / 25
74031 / 74032	Opiate Test Strip / Card (2000 ng/ml)	50 / 25
74033 / 74034	Phencyclidine Test Strip / Card	50 / 25
74035 / 74036	Marijuana (THC) Test Strip / Card	50 / 25
74037 / 74038	Tricyclic Anti-Depressant (TCA) Test Strip / Card	50 / 25
74039/ 74040	Ketamine Test Strip / Card	50 / 25
74041 / 74042	Buprenorphine Test Strip / Card	50 / 25
74043 / 74044	Oxycodone Test Strip / Card	50 / 25
74051 / 74052	Propoxyohene Test Strip / Card	50 / 25
74055 / 74056	Methylphenidate (Ritalin) Test Strip / Card	50 / 25
74057 / 74058	Fentanyl Test Strip / Card	50 / 25
74059 / 74060	Clonazepam Test Strip / Card	50 / 25
74061 / 74062	Cotinine Test Strip / Card	50 / 25
74063 / 74064	Methaqualone Test Strip / Card	50 / 25
74065 / 74066	Synthetic Marijuana (K2) Test Strip / Card	50 / 25
74075 / 74076	Ethyl Glucuronide (ETG) Test Strip / Card	50 / 25



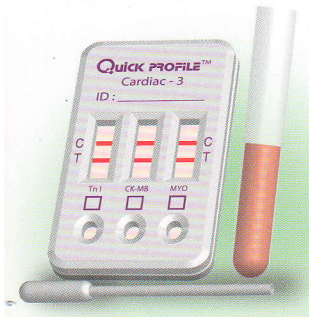
QuickProfile™ Drugs of Abuse Rapid Test

Multiple Drug Panel Test



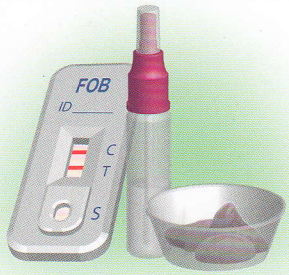
Cat. No.	Product Name	No. Per Kit
74004 / 74004-TC	DOA-2 Panel, Dip Device / Cassette Device	25
74005 / 74005-TC	DOA-3 Panel, Dip Device / Cassette Device	25
74006 / 74006-TC	DOA-4 Panel, Dip Device / Cassette Device	25
74007 / 74007-TC	DOA-5 Panel, Dip Device / Cassette Device	25
74008 / 74008-TC	DOA-6 Panel, Dip Device / Cassette Device	25
74009 / 74009-TC	DOA-7 Panel, Dip Device / Cassette Device	25
74010 / 74010-TC	DOA-8 Panel, Dip Device / Cassette Device	25
74011 / 74011-TC	DOA-9 Panel, Dip Device / Cassette Device	25
74012 / 74012-TC	DOA-10 Panel, Dip Device / Cassette Device	25
74053 / 74053-TC	DOA-11 Panel, Dip Device / Cassette Device	25
74054 / 74054-TC	DOA-12 Panel Dip Device / Cassette Device	25
74045-A	Methamphetamine / THC Test Card	25
74045-B	Methamphetamine / Opiates Test Card	25
74046	DOA Panel Test Cup, split type, up to 14 drugs	25
74046-II	DOA Panel Test Cup, up to 14 drugs	25
74074	Saliva DOA-6 Test Card (AMP/BZD/COC/MAMP/OPI/THC)	25

QuickProfile™ Cardiac Marker Rapid Test



Cat. No.	Product Name	No. Per Kit
75003	Cardiac Panel Test Card, serum/plasma (TnI / CK-MB / Myoglobin)	25
75004	Cardiac Panel Test Card, serum/plasma/whole blood (TnI / CK-MB / Myoglobin)	25
75001	Troponin I Test Card, serum/plasma	25
75002	Troponin I Test Card, serum/plasma/whole blood	25
75005	Myoglobin Test Card, serum/plasma	25
75006	Myoglobin Test Card, serum/plasma/whole blood	25
75007	CK-MB Test Card, serum/plasma	25
75008	CK-MB Test Card, serum/plasma/whole blood	25

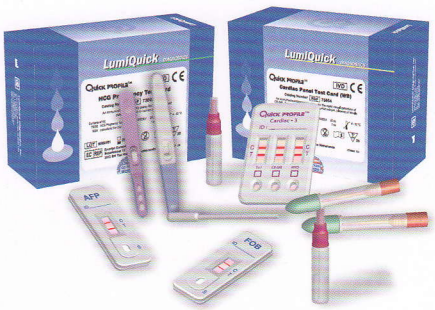
QuickProfile™ Cancer Marker Rapid Test



Cat. No.	Product Name	No. Per Kit
72001	Fecal Occult Blood Test Card	25
72002	Alpha Fetoprotein (AFP) Test Card	25
72003	Prostate Specific Antigen (PSA) Test Card	25
72009	CEA Test Card	25

QuickProfile™ Fertility Hormone Rapid Test

Cat. No.	Product Name	No. Per Kit
73001	HCG Midstream Test	25
73002	HCG Urine Test Card	25
73005	HCG Serum/Urine Test Card	25
73006	HCG Urine Test Strip	50
73003	LH Midstream Test	25
73004	LH Urine Test Card	25

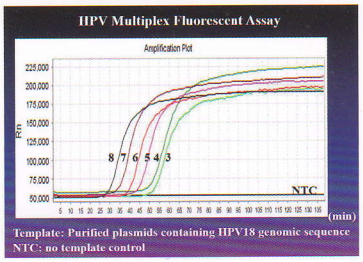


QuickProfile™ ELISA Kits

Cat. No.	Product Name	No. Per Kit
78001	HAV-IgM	96
78002	HAV-IgG	96
78003	HBsAg	96
78004	Anti-HBs (HBsAb)	96
78005	HBeAg	96
78006	Anti-HBe (HBeAb)	96
78007	Anti-HBc (HBcAb)	96
78008	Anti-HBc IgM (HBcIgM)	96
78009	HCV Antibody	96
78010	HIV Antibody	96
78011	HEV-IgM	96
78012	HEV-IgG	96
78013	HGV Antibody	96
78014	HTLV	96
78015	Treponema Pallidum (Syphilis)	96
78016	AFP	96
78017	CEA	96
78018	CA 125	96
78019	CA 15-3	96
78020	CA 19-9	96
78021	PSA	96
78022	Free PSA	96
78023	Free Beta-HCG	96
78024	Beta-2 Microglobulin	96
78025	TSH	96
78026	Ultra-Sensitive TSH	96
78027	T3	96
78028	Free T3	96
78029	T4	96
78030	Free T4	96
78031	Rubella IgG	96
78032	Rubella IgM	96
78033	Toxoplasma IgG	96
78034	Toxoplasma IgM	96
78035	CMV IgG	96

Cat. No.	Product Name	No. Per Kit
78036	CMV IgM	96
78037	HSV I IgG	96
78038	HSV I IgM	96
78039	HSV II IgG	96
78040	HSV II IgM	96
78041	H. pylori IgG, Qualitative	96
78042	H. pylori IgG, Quantitative	96
78043	H. pylori IgM	96
78044	HCG	96
78045	FSH	96
78046	LH	96
78047	Prolactin	96
78048	Visual HCG Pregnancy	96
78049	Ferritin	96
78050	HGH	96
78051	IgE	96
78052	Estradiol	96
78053	Progesterone	96
78054	Testosterone	96
78055	Troponin I	96
78056	Myoglobin	96
78057	High Sensitivity CRP	96
78058	Tuberculosis IgG	96
78059	HDV IgG	96
78060	HDV IgM	96
78061	HDV Antigen	96

Quicknostics® Molecular Diagnostic Kits



Template: Purified plasmids containing HPV18 genomic sequence
NTC: no template control

Cat. No.	Product Name	No. Per Kit
82001	HPV, high risk, isothermal real time	96/48
82002	HPV, high risk, isothermal real time with simultaneous genotyping HPV 16 and 18	96/48
82003	HPV, high risk, isothermal real time, genotyping all 15 high risk HPV	96/48
82004	HPV, high risk, real time PCR	96/48
82005	HPV, high risk, real time PCR with simultaneous genotyping HPV 16 and 18	96/48
82006	HPV, high risk, real time PCR, genotyping all 15 high risk HPV	96/48
82007	Chlamydia trachomatis, real time PCR	96/48
82008	Clostridium difficile, real time PCR	96/48
82009	Coxiella burnetii, real time PCR	96/48
82010	Mycoplasma pneumonia, real time PCR	96/48
82011	Neisseria gonorrhhoeae, real time PCR	96/48
82012	Yessinia pestis, real time PCR	96/48
82013	Bacillus Anthracis, real time PCR	96/48
82014	Francisella tularrensis, real time PCR	96/48
82015	Haemophilus, real time PCR	96/48
82016	Legionella, real time PCR	96/48
82017	Listeria, real time PCR	96/48
82018	Salmonella, real time PCR	96/48
82019	Staphylococcus, real time PCR	96/48
82020	Streptococcus, real time PCR	96/48
82021	Trichomonas vaginalis, real time PCR	

QuickProfile™ Urine Strip

Cat. No.	Product Name	No. Per Kit
76001	Urine strip, up to 11 parameters	100
76002	7 Parameter Urine Adulteration Test Strip	25

Reagents and Raw Materials

Well paired materials and reagents for infectious disease, drugs of abuse, cancer marker and cardiac marker tests to save your R&D time and cost

Contract Services

Contract services for feasibility study, product development and manufacturing

Product Specification

LumiQuick presents its products with well designed QuickProfile™, Quicknostics® and QuickStatus® packaging. The standard rapid test package contains 25 test cards or 50 test strips. The standard ELISA and CLIA kit contains 96 tests. The standard Real Time PCR kit contain 96 or 48 tests.

We also provide OEM and private label service for customers. The products can be in finished kit or bulk package format.

LumiQuick's products are for in-vitro testing for diagnostic, forensic or research use only. All the products and reagents are warranted until the date of expiration.

Order Information

When you place the order, please include at least the following information.

1.Complete shipping address
2.Complete billing address
3.Purchase order number
4.Correct catalog number, product name and quantity
5.Any special labeling and packaging instructions
6.Shipping instructions

For prompt service, please send your order by email to purchasing@lumiquick.com, fax to 1-408-855-0063, or contact your sales representative.

All orders are E.X.W from our factories. Freight charges and insurance charges are the responsibility of the customer.

LumiQuick

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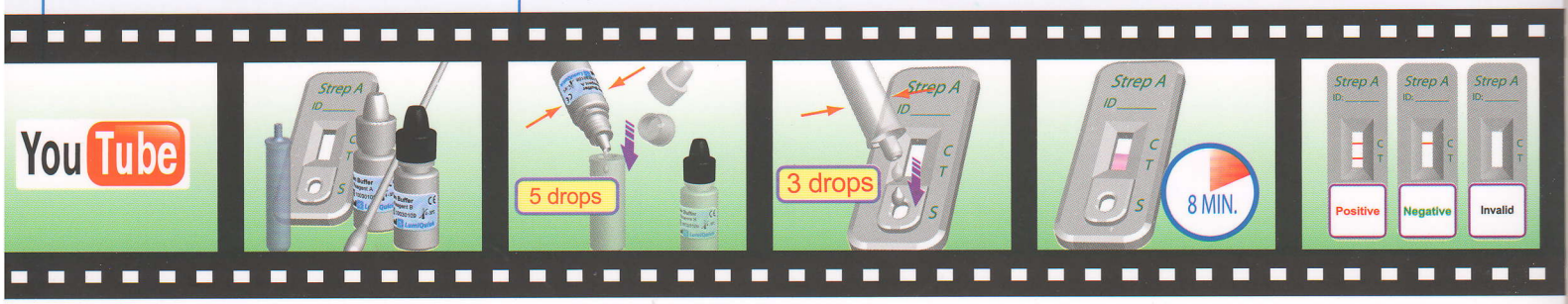

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info@lumiquick.com
Or, your local agent

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