bsi.

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
Effective Date: 2020-10-20
Latest Revision Date: 2020-08-31
Expiry Date: 2023-10-19

SCC Accredited CB-MS OCSM Accrédité CCN

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...making excellence a habit.™

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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Fax: 1-408-855-0063 www.lumiquick.com

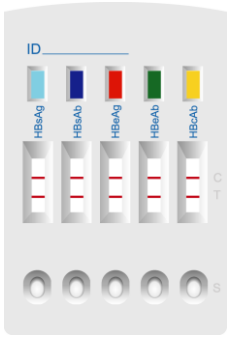
QUICK PROFILE™ HBV-5 PANEL TEST

(HBsAg, HBsAb, HBeAg, HBeAb, HBcAb-IgG)

FOR THE QUALITATIVE ASSESSMENT OF THE MARKERS OF HEPATITIS B VIRUS INFECTION IN HUMAN SERUM, PLASMA OR WHOLE BLOOD

For In Vitro Diagnostic Use Only

REF 71014-1



INTENDED USE

Quick Profile™ HBV-5 Panel Test (HBsAg, HBsAb, HBeAg, HBeAb, HBcAb-IgG), is a rapid immunochromatography assay for the qualitative detection of the markers of Hepatitis B virus including Hepatitis B virus surface antigen (HBsAg), Hepatitis B virus surface antibody (anti-HBs/HBsAb), Hepatatis B virus envelope antigen (HBeAg), Hepatatis B virus envelope antibody (HBeAb/anti-HBe) and Hepatatis B virus core antibody IgG (HBcAb-IgG) in human serum, plasma or whole blood specimens. It is intended for use in medical institution as an aid for diagnosis and management of patients related to infection with hepatitis B as well for screening of blood donors or blood products.

SUMMARY

Hepatitis B virus (HBV) is an enveloped; double- stranded DNA virus belonging to the Hepadnaviridae family and is recognized as the major cause of blood transmitted hepatitis together with hepatitis C virus (HCV). Infection with HBV induces acute or chronic liver diseases and in some cases that can lead to cirrhosis and carcinoma of the liver. Hepatitis B surface antigen or HBsAg, which was previously described as Australia antigen is the most important protein of the envelope of Hepatitis B Virus. The surface antigen contains the determinant “a”, common to all known viral subtypes, immunologically distinguished in two distinct subgroups (ay and ad). HBV has 10 major serotypes and four HBsAg subtypes have been recognized *(adw, ady, ayw,* and *ayr*). HBsAg can be detected 2 to 4 weeks before the ALT levels become abnormal and 3 to 5 weeks before symptoms develop.

TEST PRINCIPLE

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 rehydrating 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.

HBsAb test is a double antigen sandwich immunoassay. Colloidal gold conjugated HBsAg complexes are dry-immobilized in the test device. When the sample is added, it migrates by capillary diffusion through the strip rehydrating the gold conjugate complexes. If present, HBsAb 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 HBsAg immobilized there and a visible red line appears. If there is no HBsAb 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-HBsAg antibody aggregating a red line, which indicates the validity of the test.

HBeAg test is a double antibody sandwich immunoassay. Colloidal gold conjugated anti-HBeAg antibody complexes are dry-immobilized in the test device. When the sample is added, it migrates by capillary diffusion through the strip rehydrating the gold conjugate complexes. If present, HBeAg 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-HBeAg antibodies immobilized there and a visible red line appears. If there is no HBeAg 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.

HBeAb test is a competitive immunoassay. Colloidal gold conjugated anti-HBeAg antibody complexes are dry-immobilized in the test device. When the specimen is added, it migrates with the gold conjugate complexes by capillary diffusion through the strip. If present, HBeAb will compete with gold conjugate complexes for the limited amount HBeAg immobilized in the Test Zone (T). It will prevent the gold conjugate complexes from reacting with HBeAg and no red line appears in the Test Zone (T). If there is no HBeAb in the specimens, gold conjugate complexes will react with HBeAg and a visible red line appears. To serve as a procedural control, a red line will always appears in the Control Zone (C) which indicates the validity of the test.

HBcAb-IgG test utilizes the principle of Immuno-chromatography. Mouse anti-human IgG antibodies are immobilized on the nitrocellulose membrane test lines zone. As the test sample flows through the membrane within the test device, the colored–HBcAg specific recombinant antigen-colloidal gold conjugate complexes with specific IgG antibodies of HBcAg, if present in the sample. This complex moves further on the membrane to the test region where it is captured by the anti-human IgG antibodies coated on the membrane leading to formation of a colored band, which indicates a positive test results. Absence of this colored band in the test window indicates a negative test result. A built-in control line will always appear in the test window when the test has performed properly, regardless of the presence or absence of anti-HBcAg IgG antibodies in the specimen.

MATERIAL PROVIDED

1. Quick Profile™ HBV Panel Test (HBsAg, HBsAb, HBeAg, HBeAb, HBcAb-IgG)
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

Store the test device at 4 to 30^{o}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, 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 specimans 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. Whole blood samples should be refrigerated at 2–8^{o}C in stead of being frozen. 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.

PROCEDURE

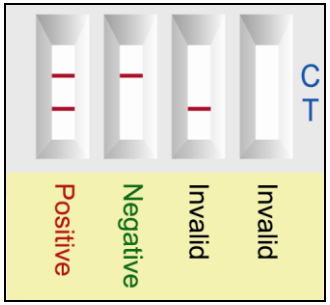
1. Bring all materials and specimens to room temperature.
2. Remove the test device from the sealed foil pouch.
3. Place the test device on a flat horizontal surface and label the test device with specimen identity.
4 Using the transfer pipet to draw up the sample, dispense 2 drops (80-100 μl) of sample in a vertical position into the each sample well individually.
5. Read the result at 20 minutes after adding the sample.

Note: *Results read after 30 minutes may not be accurate.*

INTERPRETATION OF RESULTS

Mode 1

HBsAg, HBsAb, HBeAg, HBcAb-IgG



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

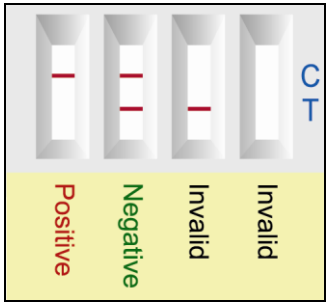
One colored bands appears in the Control Zone (C) within 20 minutes. No colored band appears in the Test Zone (T). The test result is negative and valid.

Invalid

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.

Mode 2

HBeAb



Positive

One colored bands appears in the Control Zone (C) within 20 minutes. No colored band appears in the Test Zone (T). The test result is positive and valid. If a very faint colored band appears in the Test Zone (T), the test result should be considered as positive result.

Negative

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 negative and valid.

Invalid

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.

PERFORMANCE CHARACTERISTICS:

In a clinical evaluation of the performance of Quick Profile™ HBV Panel Test, using 1249 ELISA confirmed samples, the positive agreement, negative agreement and the overall accuracy of each HBV analyte are summarized as the table.

Item	Positive Agreement (%)	Negative Agreement (%)	Accuracy (%)
HBsAg	99.6 (467/469)	99.6 (777/780)	99.6 (1244/1249)
Anti-HBs	97.6 (522/535)	98.2 (701/714)	97.9 (1223/1249)
Anti-HBc	97.1 (642/661)	97.8 (575/588)	97.4 (1217/1249)
HBeAg	99.4 (159/160)	99.6 (1085/1089)	99.6 (1244/1249)
Anti-HBe	96.9 (372/384)	98.8 (855/865)	98.2 (1227/1249)

LIMITATIONS

1. Negative results do not rule out the possibility of hepatitis B virus exposure or infection. Infection through recent exposure to HBV may not be detectable.
2. A test giving an invalid result should be repeated.
3. HBV panel test is a qualitative assay. The line intensity cannot be assumed to correlate with quantitative levels.

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 microbiological and biomedical laboratories. HHS Publication(NIH) 88-8395. Washington: U.S. Government Printing Office, May 1988.

IVD

4°C 30°C

LumiQuick Diagnostics, Inc.
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Santa Clara, CA 95054 USA
Tel : (408) 855.0061
Fax: (408) 855.0063
Email: info@lumiquick.com
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Movies available at YouTube : www.youtube.com/lumiquick