QUICK PROFILE™ HBsAg TEST

FOR THE QUALITATIVE ASSESSMENT OF HBsAg IN HUMAN SERUM, PLASMA OR WHOLE BLOOD

REF 71003 HBsAg Test Strip

REF 71004 HBsAg Test Card

For In Vitro Diagnostic Use Only

INTENDED USE
QuickProfile™ HBsAg Test is an immunochromatography assay for the qualitative detection of Hepatitis B virus surface antigen (HBsAg) in human serum, plasma or whole blood specimen.

TEST PRINCIPLE
QuickProfile™ HBsAg Test is a double antibody sandwich immunoassay. Colloidal gold conjugated anti-HBsAg antibody complexes are dry-immobilized in the test device. When the sample is added, it migrates by capillary diffusion through the strip re-hydrating the gold conjugate complexes. If present, HBsAg will react with the gold conjugate complexes forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by anti-HBsAg antibodies immobilized there and a visible red line appears. If there is no HBsAg in sample, no red line will appear in the Test Zone (T). The gold conjugate complexes will continue to migrate alone until they are captured in the Control Zone (C) by immobilized goat anti-mouse IgG antibody aggregating a red line, which indicates the validity of the test.

MATERIALS PROVIDED
1. QuickProfile™ HBsAg Test
2. Instructions for use
3. Disposable transfer pipet

MATERIALS REQUIRED BUT NOT SUPPLIED
1. Whole blood or plasma: Vacutainer tube, or other appropriate tube, containing heparin or EDTA as an anticoagulant
2. Serum: Vacutainer tube, or other appropriate tube, without anticoagulant
3. Timer or clock

STORAGE
The sealed pouches in the test kit may be stored between 4-30ºC for the duration of the shelf life as indicated on the pouch. The test must be used immediately after being removed from the sealed pouch.

PRECAUTIONS
1. This kit is **for *in vitro*** diagnostic use only.
2. This kit is for ***PROFESSIONAL*** use only.
3. Read the instructions carefully before performing the test.
4. This product does not contain any human source materials.
5. Do not use kit contents after the expiration date.
6. Handle all specimens as potentially infectious.
7. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. When the assay procedure is completed, dispose of specimens after autoclaving them at 121° C for at least 20 min. Alternatively, they can be treated with 0.5% Sodium Hypochlorite for 1-2 hours before disposal.
8. Do not pipette by mouth. Do not smoke, eat or drink in areas where reagents or specimens are handled.

SPECIMEN COLLECTION AND PREPARATION
1. The serum, plasma or whole blood specimen should be collected under standard laboratory conditions.
2. Heat inactivation of specimens, which may cause hemolysis and protein denaturation, should be avoided.
3. Patient samples performed best when tested immediately after collection. If specimens are to be stored, the red blood cells should be removed to avoid hemolysis. If the sample cannot be tested within 24 hours, serum or plasma should be frozen until the test can be performed. Allow sample to reach room temperature before proceeding.
4. Sodium azide can be added as a preservative up to 0.1% without effecting the test results.

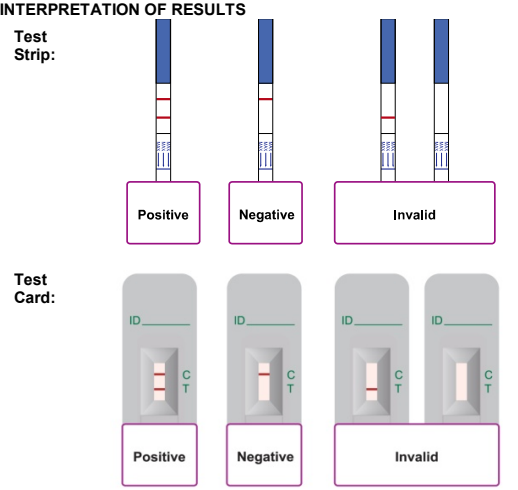
PROCEDURE

For HBsAg Test Strip (Catalog Number: 71003)
1. Bring all materials and specimens to room temperature.
2. Remove the test strip from the sealed foil pouch.
3. Label the test strip with specimen identity by writing the ID on the top label of the strip.
4. Place the test strip on a flat horizontal surface.
5. Use the transfer pipet to draw up the sample.
6. Hold the transfer pipet in a vertical position over the sample pad and dispense 2 drops (80-100 µl) of sample onto the sample pad.
7. Read the result at 20 minutes after adding the sample.

For HBsAg Test Card (Catalog Number: 71004)
1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Label the test card with specimen identity on the "ID ____ " area of the cassette.
4. Place the test card on a flat horizontal surface.
5. Use the transfer pipet to draw up the sample.
6. Hold the transfer pipet in a vertical position over the sample well and dispense 2 drops (80-100 µl) of sample into the sample well.
7. Read the result at 20 minutes after adding the sample.

Note: Some positive samples may show positive results before 20 minutes.
Results after 30 minutes may not be accurate.

INTERPRETATION OF RESULTS



Positive:
Two colored bands appear within 20 minutes. One colored band appears in the Control Zone (C) and another colored band appears in the Test Zone (T). The test result is positive and valid. No matter how faint the colored band appears in the Test Zone (T), the test result should be considered as positive result.

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

Invalid result:
No colored band appears in the Control Zone (C) within 20 minutes. The test result is invalid. Repeat the test with a new test device.

QUALITY CONTROL
1. The control band is an internal reagent for procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials are not provided with this test kit but may be commercially available.

LIMITATIONS
1. The test is for in vitro diagnostic use only.
2. Negative results do not rule out the possibility of hepatitis B exposure or infection. Infection through recent exposure to HBV may not be detectable.
3. The presumptive positive result obtained with QuickProfile™ HBsAg Test alone cannot be the final diagnosis of hepatitis B infection. As in case of all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test but should rather be made after all the clinical findings have been evaluated.
4. This test is intended ONLY for testing of an individual serum, plasma or whole blood sample. DO NOT use it for testing of other body fluids or pooled blood samples.
5. The test is for qualitative detection of HBsAg in human serum, plasma or blood sample and does not indicate the quantity of the antibodies.

PERFORMANCE CHARACTERISTICS:
Sensitivity:
QuickProfile™ HBsAg Test can detect HBsAg with a concentration of 1.0 ng/ml.

Accuracy:
Twelve hundred and forty-nine (1249) ELISA confirmed samples, including four hundred and sixty-nine (469) positive samples and seven hundred and eighty (780) negative samples were used for the clinical evaluation of QuickProfile™ HBsAg Test. The results are summarized in the following table. The sensitivity, specificity and accuracy are all 99.6%.

	ELISA HBsAg Test		
QuickProfile™ HBsAg Test		Positive	Negative
	Positive	467	3
	Negative	2	777
	Agreement	99.6%	99.6%

BIBLIOGRAPHY

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

IVD 4°C 30°C

LumiQuick Diagnostics, Inc.
2946 Scott Blvd.
Santa Clara, CA 95054 USA
Tel : (408) 855.0061
Fax: (408) 855.0063
Email: info@lumiquick.com
www.lumiquick.com