# HBsAg Rapid Test Cassette (Serum/Plasma) Instructions for Use

| REF IHBSG-C31 | English |
|---|---|

*Rapid test for the qualitative detection of the Hepatitus Surface Antigen (HBsAG) in human serum or plasma.*
*For professional in vitro diagnostic use only.*

**【Intended Use】**
The HBsAg rapid test cassette (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of hepatitis B surface antigen in serum or plasma. The HBsAg rapid test cassette (Serum/Plasma) is not intended for the screening of blood donors and donated organs

**【Overview】**
HBV is a hepatotropic virus that belongs to the hepadnavirus family. Its DNA genome is replicated via a reverse transcriptase mechanism. [1] The complex antigen on the surface of HBV is called HBsAg. Earlier names include Australia antigen or Au antigen.1 The presence of HBsAg in serum or plasma is indicative of an active acute or chronic hepatitis B infection. In the case of a typical hepatitis B infection, HBsAg is detected as early as 2 to 4 weeks before the development of abnormal ALT levels and as early as 3 to 5 weeks before the onset of symptoms or jaundice. HBsAg has four major subtypes: adw, ayw, adr and ayr. Due to the antigen heterogeneity of the determinant, there are 10 major serotypes of hepatitis B virus.
The HBsAg Rapid Test Cassette is a rapid test for the qualitative detection of HBsAg in serum or plasma specimens. The test uses a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in serum or plasma.

**【Principle】**
The HBsAg Rapid Test Cassette (Serum/Plasma) is a qualitative, solid phase, two-site sandwich immunoassay for the detection of HBsAg in serum or plasma. The membrane is pre-coated with anti-HBsAg antibodies in the test area of the cassette. During the test procedure, the serum or plasma sample reacts in the absorption pad with particles coated with anti-HBsAg antibodies. The mixture flows chromatographically through the membrane by capillary action, reacts with anti-HBsAg antibodies in the test area of the cassette and produces a coloured line. The presence of the coloured line indicates a positive result, while its absence indicates a negative result. For procedural control, a coloured line always appears in the control area. This means that the specimen volume was sufficient and that the liquid has completely penetrated the membrane.

**【REAGENTS】**
The test cassette contains particles coated with anti-HBsAg antibodies and a membrane coated with anti-HBsAg antibodies.

**【PRECAUTION】**
**Please read all the information in these instructions for use before carrying out the test.**

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch or closed canister until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test should be discarded according to local regulations.
5. The test should be performed within one hour after opening the pouch. A relative humidity >60% and a temperature > 30 ℃ can adversely affect the results. .

**【STORAGE AND SHELF LIFE】**
Store the packaged test cassette at room temperature or refrigerated (2-30°C). The test cassette can be used until the expiry date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use after the expiry date.

**【SPECIMEN COLLECTION AND PREPARATION】**

1. The HBsAg Rapid Test Cassette (Serum/Plasma) can be performed using serum or plasma.
2. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear and non-haemolysed samples.
3. Testing should be carried out immediately after sample have been collected. Do not leave the sample at room temperature for a longer period of time. The sample can be stored at 2-8°C for up to 3 days or at -20°C for up to 6 months.
4. Bring samples to room temperature before use. Frozen samples must be completely thawed and mixed before use. Samples must not be frozen and thawed repeatedly.

**【MATERIALS】**

**Materials Provided**

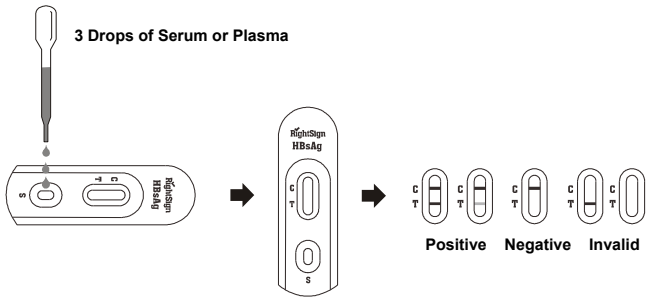
Test cassettes | Disposable pipettes | Package Insert

**Materials Required But Not Provided**

Collection tubes | Centrifuge | Stopwatch

**【DIRECTIONS FOR USE】**

1. Bring the pouch to room temperature before opening. Remove the test cassette from the sealed pouch and use it within one hour.
2. Hold the pipette vertically and add **3 drops of serum or plasma (approx. 120 µl)** to the sample well of the test cassette. Start the stopwatch. (See the illustration below)
3. Wait for the coloured line(s) to appear. Read the test result after **15 to 30 minutes**. Do not evaluate the test result after **30 minutes.**




**【EVALUATION OF RESULTS】**
(See the illustation above)
**POSITIVE: Two distinct coloured lines appear**, one line in the control area (C) and another line in the test area (T). NOTE: The intensity of the coloured line in the test area (T) may vary according to the concentration of HBsAg in the sample. Therefore, any shade of red in the test area (T) should be considered a positive result.
**: A coloured line appears in the control area (C)**. No visible coloured line appears in the test area (T).
**INVALID: No coloured line appears in the control area (C)**. Insufficient sample volume or incorrect procedural techniques are the most likely causes. Review the procedure and repeat the test with a new test cassette. If the problem persists, immediately stop further use of the test pack and contact your local distributor.

**【QUALITY CONTROL】**
The test includes an internal procedural control. The presence of a red line in the control area (C) is this internal procedural control. It confirms that the liquid has completely penetrated the membrane.
Control standards are not included in this test kit. It is nevertheless recommended, as part of good laboratory practice, to use a positive control (10 ng/ml HBsAg) and a negative control (0 ng/ml HBsAg) to verify test performance and correct test performance.

**【LIMITATIONS】**

1. The HBsAg rapid test cassette is For professional in vitro diagnostic use only. The test is intended for the detection of HBsAg in serum or plasma. Neither a quantitative value nor the rate of increase of a HBsAg concentration can be detected by this qualitative test.
2. The HBsAg rapid test cassette only indicates the presence of HBsAg in the sample. It should not be used as the sole criterion for diagnosing hepatitis B virus infection.
3. As with all diagnostic tests, evaluation by the physician should be done only after taking into account all available clinical information.
4. The HBsAg rapid test cassette can detect HBsAg from a concentration of
5. 1 PEI ng/ml in samples. If the test result is negative and clinical symptoms persist, additional subsequent testing using other clinical methods is recommended. A negative result at no time completely excludes a possible hepatitis B virus infection.

**【EXPECTED VALUES】**
The HBsAg rapid test cassette (serum/plasma) has been compared with a leading commercial HBsAg EIA test. The correlation between these two systems is more than 98%.

**【PERFORMANCE CHARACTERISTICS】**

**Sensitivity**
The HBsAg Rapid Test Cassette (Serum/Plasma) has been tested with a sensitivity panel ranging from 0 to 300 ng/ml. All 10 HBsAg subtypes produced positive results with the HBsAg Rapid Test Cassette (Serum/Plasma). The test can detect HBsAg from a concentration of 1 PEI ng/ml in serum or plasma.

**Specificity**
Antibodies used for the HBsAg Rapid Test Cassette (Serum/Plasma) were developed against whole hepatitis B antigen isolated from the hepatitis B virus. Specificity of the HBsAg rapid test cassette (serum/plasma) was tested with laboratory strains of hepatitis A and hepatitis C. All laboratory strains yilelded negative results..
The results show that the relative sensitivity of the HBsAg rapid test cassette (serum/plasma) is 99.8% and the relative specificity is 99.6%. More than 30 seroconversion panels were evaluated with the test.

| Method | | EIA | | Total Results |
|---|---|---|---|---|
| HBsAg Test Cassette (Serum/Plasma) | Results | Positive | Negative | |
| | Positive | 424 | 6 | 430 |
| | Negative | 1 | 1606 | 1607 |
| Total Results | | 425 | 1612 | 2037 |

Relative Sensitivity: 99,8% (95%CI*: 98,7%-100%)
Relative Specificity: 99,6% (95%CI*: 99,2%-99,9%)
Accuracy: 99,7% (95%CI*: 99,3%-99,9%)
*Confidence Intervals

The results show that the diagnostic sensitivity of the HBsAg rapid test cassette (serum/plasma) is 99.8% and the diagnostic specificity is 99.6%.

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**Precision**

**Intra-Assay**
Within-run precision was determined using 10 replicates of four samples containing 0 ng/ml, 1 ng/ml 7 ng/ml and 20 ng/ml HBsAg. The negative and positive values were correctly identified >99.9% of the time.

**Inter-Assay**
Between-run precision was determined using the same 4 samples containing 0 ng/ml, 1 ng/ml, 7 ng/ml and 20 ng/ml HBsAg in 10 independent tests. Using negative samples, low positive samples and high positive samples, three different batches of the HBsAg rapid test cassette (serum/plasma) were tested over a period of 3 months. The samples were correctly identified >99.9% of the time.

**Cross-Reactivity**
The HBsAg rapid test cassette (serum/plasma) was tested with positive HAMA, rheumatoid factor (RF), HAV, syphilis, HIV, H. pylori, MONO, CMV, Rubella, HCV, HEV and TOXO samples. The results showed no cross-reactivity.

**Interfering Substances**
The HBsAg rapid test cassette (serum/plasma) was tested for possible interaction of visibly haemolysed and lipemic samples. No interferences were observed. Furthermore, no interferences were observed with the following substances at the specific concentration mentioned:

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| Ascorbic acid: | 20 mg/ml | Paracetamol: | 20 mg/dL |
| Hemoglobin: | 1000 mg/dL | Aspirin: | 20 mg/dL |
| Gentisic acid: | 20 mg/dL | Methanol: | 10 % |
| Oxalic acid: | 60 mg/dL | Creatine: | 200 mg/dL |
| Bilirubin: | 1000 mg/dL | Albumin: | 2000 mg/dL |
| Uric acid: | 20 mg/dL | Caffeine: | 20 mg/dL |

**【Bibliography】**

1. Zoulim F, Lebossé F, Levrero M. Current treatments for chronic hepatitis B virus infections. Curr Opin Virol 2016;18:109-116.
2. Ott, J. J., Stevens. G. A., Groeger, J. & Wiersma, S. T. Global epidemiology of hepatitis B virus infection: new estimates of age-specific HBsAg seroprevalence and endemicity. Vaccine 30, 2212-2219(2012).
3. Shevanthi,N., Mark, T., Elisa, S., etc. Requirements for global elimination of hepatitis B: a modelling study. The Lancet Infectious Diseases, Volume 16, Issue 12, December 2016, Pages 1399-1408.


**Symbol Index**

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| | Consult instructions for use | Σ | Tests per kit | EC REP | Autthorized Representative |
| IVD | For *in vitro* diagnostic use only | | Use by | | Do not reuse |
| 2°C 30°C | Store between 2-30°C | LOT | Lot number | REF | Catalog # |
| | Do not use if package is damaged | | | | |


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CE 1434

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