Lab Rapid HBsAg

Insert

Ref.: 716

Intended Use . System for qualitative, rapid detection of hepatitis B virus surface antigen (HBsAg) in serum, plasma and human whole blood samples.

Professional use.

[For in vitro diagnostic use only].

Principle . The system consists of a membrane on which anti-HBsAg antibodies have been immobilized in the test region. When carrying out the test, the sample is placed to react with the conjugate that contains particles linked to anti-HBsAg antibodies. The conjugate complexes with the HBsAg present in the sample. After adding the buffer, the antigen-conjugate complex migrates across the membrane and finds the test region in which the anti-HBsAg antibody is immobilized. Thus, a colored line is formed indicating the presence of HBsAg antigen in the sample. The absence of a test line indicates a negative result as long as the control line, used as control of the procedure, appears in the test.

Summary . The Lab Rapid HBsAg system is an immunochromatographic method that allows the detection of hepatitis B virus surface antigen (HBsAg) through a simple, fast and easy-to-interpret procedure in serum, plasma or whole blood samples. The use of monoclonal and polyclonal anti-HBsAg antibodies guarantee the high sensitivity and specificity of the product.

Methodology . Immunochromatography.

Reagents

1. Reaction plates or strips - Store between 2 - 30°C.
Do not freeze. It contains anti-HBsAg1 particle conjugate, anti-HBsAg antibody 2 and control antibody applied or immobilized in the membrane.

2. Buffer - Store between 2 and 30°C.
Do not freeze. It contains phosphate buffer, sodium chloride, high molecular weight polypeptide and < 0.1% isothiazolinone.

Unopened reagents, when stored under the indicated conditions, are stable until the expiration date printed on the label. The Buffer, once opened, is stable for 2 months. While handling, reagents are subject to chemical and microbial contamination that can cause reduced stability.

Precautions and warnings

The product should never be frozen or exposed to a temperature above 30°C.

Avoid exposure of reaction plates or strips to ambient moisture.

The usual safety precautions should be used when handling reagents and samples.

The sample volume informed in the ''Procedure'' section of this instruction for use must be strictly followed. Changes in the use of this volume can result in erroneous results.

Since no known test can guarantee that blood samples do not transmit infections, they should all be considered as potentially infectious. Thus, when handling them, biosafety rules must be followed.

The Buffer contains isothiazolinone which is toxic. Special care must be taken to avoid ingestion and, in case of eye contact, wash your eyes immediately with abundant water and seek medical assistance.

To dispose reagents and biological material, we suggest applying local, state or federal protection standards.

Required material and not provided

1. Chronometer.

Samples

Serum, plasma (EDTA, citrate, oxalate, heparin) or whole blood (EDTA, citrate, oxalate, heparin).

The analyte is stable for 3 days at 2-8°C. Store the serum or plasma sample at temperature equal to or lower than minus 20°C for up to 6 months in a hermetically closed container to prevent evaporation.[3]
The whole blood sample must not be frozen.
Ensure that the samples are thawed and homogenized before use. Suspended particles must be removed by centrifugation.
Samples must not be inactivated by heat as they may produce incorrect results.
Do not use samples with signs of contamination or frozen and thawed samples repeatedly.
Do not use hemolyzed and/or lipemic samples.

A Standard Operating Procedure (SOP) should be created to establish adequate procedures for sample collection, preparation and storage. We emphasize that the errors due to the sample can be much larger than the errors that occurred during the analytical procedure.

Interferences

No false positive results were observed in samples positive for anti-HAV, anti-HCV, anti-HEV, anti-HIV, Syphilis, Toxoplasmosis, Rubella, CMV, *H. pylori*, Rheumatoid factor, HAMA and MONO.

No interference was observed for samples containing hemoglobin up to 2000 mg/dL, bilirubin up to 1000 mg/dL and albumin up to 2000 mg/dL.

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Procedure

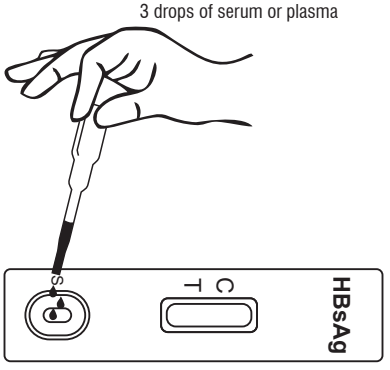
Samples and product must be at room temperature at the time of testing.

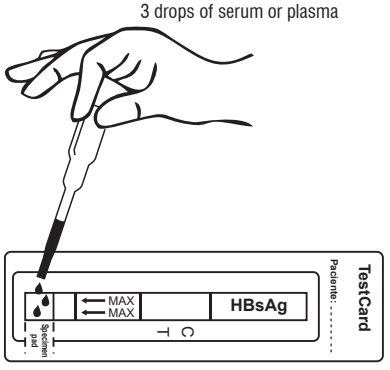
Reaction plates

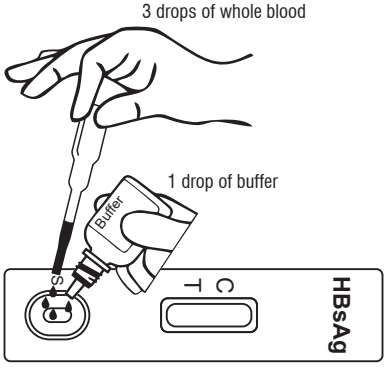
1. Remove the reaction plate from the protective envelope, identify it properly and place it on a horizontal surface.
2. For serum or plasma, with the aid of a pipette, add 3 drops (0.075 mL) to the sample well (S); for whole blood, with the aid of a pipette, add 3 drops (0.075 mL) and 1 drop (0.04 mL) of the Buffer to the sample well (S).
3. Perform the reading of the results between 15 and 30 minutes. Do not do the reading after 30 minutes.

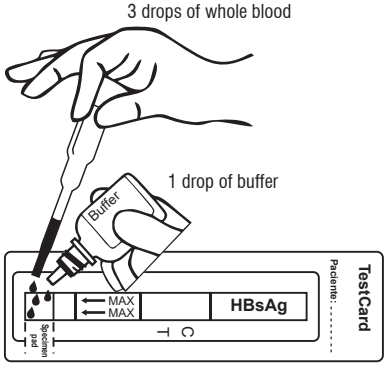
Reaction strips

1. Place the support card (Test Card) on a horizontal surface and properly identify it.
2. Remove the film from the adhesive part by pulling the part indicated as ''Peel here''.
3. Remove the reaction strip from the protective envelope and place it on the support card.
4. For serum or plasma, with the aid of a pipette, add 3 drops (0.075 mL) to the sample site; for whole blood, with the aid of a pipette, add 3 drops (0.075 mL) and 1 drop (0.04 mL) of the Buffer at the sample site.
5. Perform the reading of the results between 15 and 30 minutes. Do not do the reading after 30 minutes.









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INTERPRETING THE RESULTS

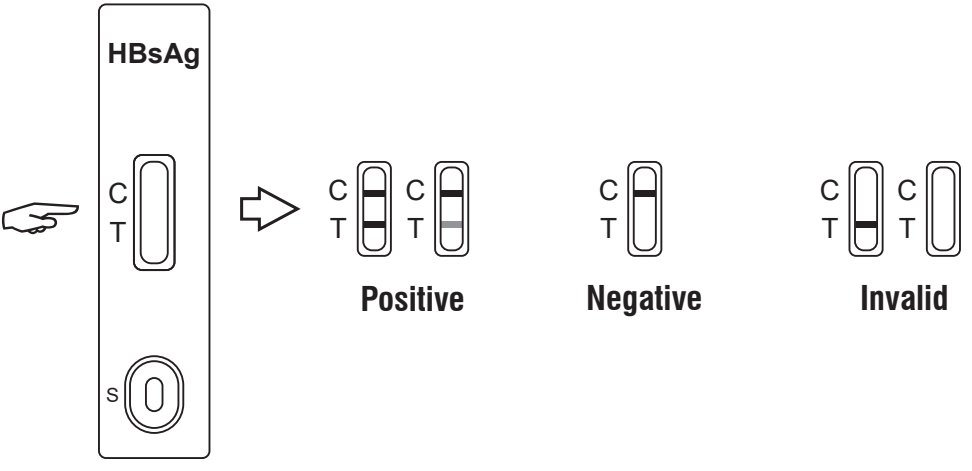
Positive
Formation of a colored line in the control region (C) and in the test region (T).

Negative
Formation of a colored line in the control region (C) and absence of line in the test region (T).

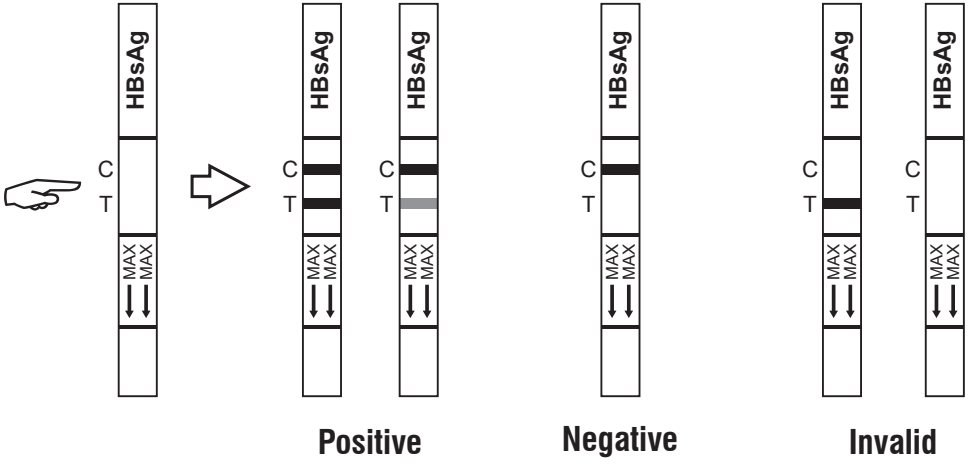
Samples that present negative result at 15 minutes must have the result confirmed at 30 minutes.

Invalid
The absence of a line in the control region (C) indicates procedural error or system deterioration. Review the procedure and repeat the test with a new plate or reaction strip.

Reaction Plates



Reaction Strips



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As it is a screening test, any sample that shows a positive result in a rapid test must also be analyzed by complementary methodology such as molecular tests or immunoassay for detection of total anti-HBc, according to the flowcharts described in the Technical Manual for Diagnosis of Viral Hepatitis in Adults and Children approved by SVS/MS Ordinance no. 25, dated December 1, 2015.[4]

This product is a screening test, so a negative result does not rule out the possibility of HBV infection. If the suspicion of HBV infection persists, a new sample should be tested according to the recommendations of the Technical Manual for Diagnosis of Viral Hepatitis approved by Ordinance nº 25, dated December 1th, 2015.4 For interpretation of the test result, other clinical information must be taken into account.

Internal Quality Control[5] . The laboratory must maintain an internal quality control program that clearly defines the applicable regulations, objectives, procedures, criteria for quality specifications and tolerance limits, corrective actions and record of activities.

The formation of a colored line in the control region is indicative of adequate performance of the procedure. To ensure that the system has not been adversely affected and maintains the established performance levels, we suggest associating a quality control system using, daily, known samples, one positive and one negative.

Performance characteristics[7]

Comparative Studies . Comparison studies have been conducted using 560 positive and negative samples tested with the Lab Rapid HBsAg - Labtest system and and with a commercially available ELISA methodology product (comparative method), by obtaining the results presented in the following tables.

	Lab Rapid HBsAg - Labtest	
Comparative Method	Positive	Negative
Positive	149	1
Negative	1	409

Relative sensitivity: 99.3%
Relative Specificity: 99.8%
Efficiency: 99.6%
Kappa Index: 0.99

The Kappa Index greater than 0.80 indicates an excellent concordance6 between the methods, showing that the Lab Rapid HBsAg - Labtest system is substantially equivalent to the comparative method.

Repeatability - Intra-assay precision . The intra-assay inaccuracy was verified through the evaluation of three replicates of six samples, of which five were positive with concentrations of 1, 2, 5, 12 and 20 ng/mL and one negative. Negative and positive results found showed a perfect agreement with the expected results.

Reproducibility - Interassay precision . The total inaccuracy was verified through the evaluation of ten replicates of six serum samples and six plasma samples, of which five were positive with concentrations of 1, 2, 5, 12 and 20 ng/mL and one negative. The tests were performed for ten days. The results found showed a perfect agreement with the expected results.

Pro-zone Effect . The product does not present pro-zone effect in samples positive for HBsAg with concentration up to 500 ng/mL or 1000 IU/mL.

Methodological sensitivity . The method is capable of detecting quantities greater than or equal to 1 ng/mL or 2 IU/mL.

The time of execution of the test can interfere in the concentration of HBsAg present in the sample, such that the methodological sensitivity of the product Lab Rapid HBsAg - Ref. 716 could be lower.

Clinical significance . Viral hepatitis are systemic diseases that mainly involve the liver and have the hepatitis B virus (HBV) as one of the causing agents. HBV belongs to the Hepadnaviridae family and is capable of infecting different animals.[1] The antigen found on the HBV surface is called HBsAg. It was discovered in 1966 and was called Australia or Au antigen.[2] HBsAg is one of the five serological markers of the HBV infection and its presence in the sample indicates active infection, which may be acute or chronic. In a typical HBV infection, HBsAg will be detected between 2 to 4 weeks before ALT / GTP levels become abnormal and 3 to 5 weeks before the appearance of symptoms or jaundice. There are four main subtypes for HBsAg: adw, ayw, adr and ayr and due to the heterogeneity of the antigen there are more than 10 serotypes for HBV. HBV is transmitted parenterally and, mainly, sexually, which classifies hepatitis B as an STI. Vertical transmission (from mother to child) also occurs in regions of high endemicity.[1]

References

1. Brazil. Ministry of Health. Secretariat of Health Surveillance. Sexually Transmitted, HIV/Aids and Viral Hepatitis Infection Surveillance, Prevention and Control Department. Technical Manual for Diagnosis of Viral Hepatitis / Ministry of Health, Secretariat of Health Surveillance, Sexually Transmitted, HIV/Aids and Viral Hepatitis Infection Surveillance, Prevention and Control Department. - Brasília: Ministry of Health, 2016. 121 p.: il.

2. Blumberg, B.S. The Discovery of Australian Antigen and its relation to viral hepatitis. Vitro. 1971; 7: 223.

3. Recommendations of the Brazilian Clinical Medicine / Laboratory Medicine Society (SBPC/ML). Collection and preparation of biological samples. 2014.

4. Brazil. Ministry of Health. Secretariat of Health Surveillance. SVS/MS Ordinance no. 25, dated Dececmber 1, 2015. It approves the Technical Manual for Diagnosis of Viral Hepatitis in Adults and Children, available at the electronic address www.aids.gov.br, which contains the recommended flowcharts for different scenarios and situations that suit the plurality of conditions and the diversity of public and private health services. Federal Official Gazette (Diario Oficial da União) of the Federative Republic of Brarzil, December 2, 2015. Available at <www.saude.gov.br/svs/>.

5. Westgard JO, Barry PL, Hunt MR, Groth T. Clin Chem 1981;27:493-501.
6. Landis, J. Richard; KOCH, Gary G. The measurement of observer agreement for categorical data. Biometrics, p. 159-174, 1977

7. Labtest: File on Data

Presentation

Product	Reference	Content	
Lab Rapid HBsAg	716C-20	Reaction Plate	20 Units
		Buffer	1 X 3.0 mL
	716S-20	Reaction Strips	20 Units
		Buffer	1 X 3.0 mL

For information on other commercial presentations, please visit www.labtest.com.br or contact the Customer Service.

Customer information

[Warranty Conditions]

Labtest Diagnóstica guarantees the product performance, within the specifications, until the expiration date indicated on the labels, provided that the care for use and storage indicated on the labels and in these instructions are correctly followed.

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Símbolos utilizados com produtos diagnósticos in vitro

Símbolos usados con productos diagnósticos in vitro

Symbols used with ivd devices

 **Conteúdo suficiente para < n > testes** Contenido suficiente para < n > tests Contains sufficient for < n > tests	 **Risco biológico** Riesgo biológico Biological risk
 **Data limite de utilização (aaaa-mm-dd ou mm/aaaa)** Estable hasta (aaaa-mm-dd o mm/aaaa) Use by (yyyy-mm-dd or mm/yyyy)	 **Marca CE** Marcado CE CE Mark
 **Material Calibrador** Material Calibrador Calibrator Material	 **Tóxico** Tóxico Poison
 **Material Calibrador** Material Calibrador Calibrator Material	 **Reagente** Reactivo Reagent
 **Limite de temperatura (conservar a)** Temperatura limite (conservar a) Temperature limitation (store at)	 **Fabricado por** Elaborado por Manufactured by
 **Representante Autorizado na Comunidade Europeia** Representante autorizado en la Comunidad Europea Authorized Representative in the European Community	 **Número do lote** Denominación de lote Batch code
 **Consultar instruções de uso** Consultar instrucciones de uso Consult instructions for use	 **Controle** Control Control
 **Número do catálogo** Número de catálogo Catalog Number	 **Controle negativo** Control negativo Negative control
 **Adições ou alterações significativas** Cambios o suplementos significativos Significant additions or changes	 **Controle positivo** Control positivo Positive control
 **Produto diagnóstico in vitro** Dispositivo de diagnóstico in vitro In vitro diagnostic device	 **Controle** Control Control
 **Liofilizado** Liofilizado Lyophilized	 **Corrosivo** Corrosivo Corrosive
 **Período após abertura** Periodo post-abertura Period after-opening	 **Uso veterinário** Uso veterinario Veterinary use
 **Instalar até** Instalar hasta Install before	Ref.: 140214

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