



Abbott

Bioline®

HBsAg WB

HBsAg Rapid Test

Test rapide de HBsAg

Prueba rápida de HBsAg

Teste rápido HBsAg

ENGLISH

About the test
Introduction: The disease known as hepatitis B is caused by the infectious Hepatitis B virus (HBV). HBV alone is believed to have infected 400 million people in the world, making HBV one of the most common human pathogens. It is mainly transmitted between people through contact with infected blood, frequently from mother to baby at birth. Sexual transmission, though inefficient, is also a possible mode of transmission. There are other potential sources of transmission. A variety of serological assays may be used to detect antibodies to hepatitis B virus (anti-HBc), hepatitis B e antigen (HBeAg) and hepatitis B surface antigen (HBsAg). The sensitive and specific methods used commercially in diagnosis are the immunochromatographic, radioimmunoassay (RIA) and enzyme-linked immunosorbent assay (ELISA) for HBV infection. The sensitive and specific methods used commercially in diagnosis are the immunochromatographic, radioimmunoassay (RIA) and enzyme-linked immunosorbent assay (ELISA).

[Test principle] The membrane is pre-coated with mouse monoclonal anti-HBc IgG polyclonal on the test line region and Mouse monoclonal anti-chicken IgY on the control line region. During testing, the specimen is allowed to react with the anti-HBc antibody and the anti-chicken IgY antibody. The reaction product then moves upward on the membrane chromatographically until it reaches the cut-off line. For a reactive result, a purple-colored line will form in the test line region of the membrane. If no reaction occurs, a purple-colored line will form in the control line region of the membrane. Regardless of the presence of HsAb, chicken IgY coated gold particles will form in the test line region of the strip, continues to move across the membrane to immobilized mouse monoclonal anti-chicken IgY, then a purple-colored line will form in the control line region of the result window appears. The presence of a purple-colored line in the control line region of the result window indicates that sufficient volume of specimen has been added and that probe flow has been obtained.

[Intended use] Bioline™ HBsAg WB is an in vitro diagnostic test for the qualitative detection of Hepatitis B surface antigen, in human serum, plasma, heparin, EDTA and sodium citrate (anti-coagulant) media. Bioline™ HBsAg WB is intended only for professional use as an aid to diagnosis. Reactive specimens should be referred for additional testing.

Only by Enzyme immunoassay (ELISA) to identify hepatitis B surface antigen. Bioline™ HBsAg WB is intended for use in children and infants. Blood donation screening. Because false non-reactive results may also arise due to the lack of ability of the assay to detect HBsAg mutants. The performance of Bioline™ HBsAg WB in infants or children has not been validated.

Materials provided and active ingredients of main components

- The Bioline™ HBsAg WB contains the following items to perform the assay:
 - 30 Test devices with desiccant in individual foil pouches
 - 1 Control device
 - 2 Active ingredients of main components
 - 1 Test device includes:
 - Gold conjugate: mouse monoclonal anti-HBc IgG conjugated gold colloid (0.054±0.011 µg)
 - Control device: mouse monoclonal anti-HBc IgG (0.040±0.028 µg)
 - Test Line: Mouse monoclonal anti-HBc IgG (0.480±0.096 µg)
 - Control Line: Mouse monoclonal anti-chicken IgY (0.480±0.096 µg)

Materials required but not provided

- Microscope, protective glasses, timer, Biohazard container

Kit storage and stability

- 1. The test should be stored at a temperature between 1°C and 40°C. Do not freeze the kit or its components.
- 2. The test device is sensitive to both heat and humidity. Perform the test immediately after removing the test device from the foil pouch.
- 3. Do not use the test kit beyond its expiration date. The shelf life of the kit is indicated on the outer package.
- 4. Do not use the test kit if the pouch is damaged or the seal is broken.

Warnings

- 1. The test device is for in vitro diagnostic use. Do not reuse the test device.
- 2. The instructions must be followed exactly to achieve accurate results. Any individual performing an assay with this product must be trained in its use and must be proficient.
- 3. Do not bite by mouth, smoke, drink, or eat in areas where specimens or kit components are being handled.
- 4. Wear protective gloves when handling specimens and wash hands thoroughly afterwards.
- 5. Clean up spills thoroughly on an appropriate absorbent.
- 6. Disinfect and dispose of all specimens, reaction kits and potentially contaminated materials in a biohazardous waste.
- 7. Do not mix or interchange different specimens.
- 8. Do not eat the desiccant in the foil pouch.
- 9. Avoid spilling or allowing specimen into aerosol formation.

Specimen collection and handling

- 1. Whole blood
- 2. Using venipuncture, draw whole blood and insert it into the collection tube containing anticoagulants including heparin, EDTA and sodium citrate and centrifuge the blood to generate a plasma specimen.
- 3. Serum (using venipuncture, draw whole blood and insert it into the collection tube (NOT containing anticoagulants) and centrifuge the blood to allow blood clotting).
- 4. Centrifuge the tube to generate a serum specimen.
- 5. If plasma or serum specimens are not tested immediately, they should be refrigerated at 2 - 8°C. For storage longer than 2 weeks, freeze at -20°C and -70°C.
- 6. Do not use a blood specimen for more than 3 days; otherwise a non-specific reaction may result.
- 7. Bring plasma specimens to room temperature (15 - 40°C) prior to use.
- 8. Plasma samples
- 9. Place the sample in a dry, temperature controlled environment and insert it into the collection tube containing anticoagulants including heparin, EDTA and sodium citrate and centrifuge the blood to generate a plasma specimen.
- 10. Serum (using venipuncture, draw whole blood and insert it into the collection tube (NOT containing anticoagulants) and centrifuge the blood to allow blood clotting).
- 11. Centrifuge the tube to generate a serum specimen.
- 12. If plasma or serum specimens are not tested immediately, they should be refrigerated at 2 - 8°C. For storage longer than 2 weeks, freeze at -20°C and -70°C.
- 13. Recombinant HBsAg mutant panels (n=10)

None of the following HBsAg mutant panels was positive on the Bioline™ HBsAg WB.

Test procedure (Refer to figure)

- 1. Bring the test device to a temperature between 15 - 40°C prior to testing.
- 2. Remove the test device from the foil pouch, and place it on a flat, dry surface. Label the test device with a patient identifier.
- 3. Using a pipette, dispense 10µL of serum, plasma or whole blood specimen into the specimen well.
- 4. At the test begins to work, you will see a purple color move across the result window in the center of the test device. Interpret test results at 20 minutes.
- 5. Caution: Do not read test results after 20 minutes; late readings can yield false results.

Test interpretation (Refer to figure)

- 1. A colored line will appear at "C" in the result window to show that the test is working.
- 2. The "T" section of the result window indicates the test result.
- 3. The "N" section of the result window indicates a non-reactive result.
- 4. The "C" section of the result window indicates the control result.
- 5. Caution: Do not read the test result if the control is not visible, it is recommended to retest the test.

Performance characteristics

- This product may have performance parameters for diagnosis in clinical specimens that are expected to be early phase markers or low concentrations of HBsAg and/or HBeAg. The test may have been developed to be able to detect common markers of hepatitis B, it is limited in its ability to detect virus mutants. As a result, false non-reactive results may occur. These performance limitations can be a factor of false non-reactive results.

2. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should be made by the physician first, including retesting.

3. Due to the high cost of the Bioline™ HBsAg WB (IVD test), a faint or absent test result (false non-reactive) may occur in specimens containing high concentrations of HBsAg. In order to obtain a definitive result, all clinical and laboratory findings should be evaluated.

Test limitations

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- 3. Reproducibility of the Bioline™ HBsAg WB has been demonstrated by within-run, between-run, and batch-to-batch studies using in-house reference panels. All values were identical to reference panel acceptance criteria.

Internal quality control

The Bioline™ HBsAg WB test device has "Test line" and "Control line" on the surface of the device. The entire test line and control line in the result window are not visible before applying any specimen. The control line is used for procedural control. The control line of the RDT only shows that the active ingredients of the main components on the strip were still functional, but does not guarantee that the test kit may have deteriorated. It is recommended that the specimen be retested using a new test device.

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Reactive result: The presence of the test line (T) and the control line (C) within the result window indicates a reactive result.

Non-reactive result: The presence of only the control line (C) within the result window indicates a non-reactive result.

Invalid result: If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Instructions may not have been followed correctly or the test kit may have deteriorated. It is recommended that the specimen be retested using a new test device.

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Reactive result: The presence of the test line (T) and the



REF 01FK10W

TEST PROCEDURE / PROCÉDURE DE TEST / PROCEDIMIENTO DE LA PRUEBA / PROCEDIMENTO DO TESTE

Bioline®
HBsAg WB

HBsAg Rapid Test
Test rapide de détection de l'antigène HBsAg EN UNE ÉTAPE
Prueba rápida de HBsAg en un paso
Teste rápido HBsAg num único passo

PREPARATION / PRÉPARATION / PREPARACIÓN / PREPARAÇÃO

1 **EN** Open the package and look for the following:

1. Test device with desiccant in individual foil pouch
2. Instructions for use

FR Ouvrir l'emballage et identifier les éléments suivants :

1. Dispositif de test avec agent déshydratant conditionné dans un emballage en aluminium individuel
2. Mode d'emploi

ES Abra el paquete y busque los siguientes elementos:

1. Dispositivo de prueba con desecante en bolsa de papel aluminio individual
2. Instrucciones de uso

PT Abra a embalagem e procure o seguinte:

1. Dispositivo de teste com dessecante em bolsa de folha de alumínio individual
2. Instruções de utilização

2 **EN** Carefully read the instructions for using the Bioline™ HBsAg WB test.

FR Lire attentivement le mode d'emploi du test Bioline™ HBsAg WB.

ES Lea con atención las instrucciones de uso de la prueba Bioline™ HBsAg WB.

PT Leia cuidadosamente as instruções para utilizar o teste Bioline™ HBsAg WB.

3 **EN** Look at the expiration date on the back of the foil pouch. If the expiration date has passed, use another kit.

FR Vérifier la date de péremption à l'arrière de l'emballage en aluminium. Si elle est dépassée, utiliser un autre kit.

ES Lea la fecha de vencimiento indicada en la parte posterior de la bolsa. Si la fecha ya ha pasado, use otro kit.

PT Verifique o prazo de validade na parte posterior da bolsa de folha de alumínio. Se o prazo de validade tiver sido ultrapassado, utilize outro kit.

4 **EN** Open the foil pouch and look for the following:

1. Test device
2. Desiccant

Then, label the device with the patient identifier.

FR Ouvrir l'emballage en aluminium et identifier les éléments suivants :

1. Dispositif de test
2. Agent déshydratant

Apposer ensuite une étiquette indiquant l'identifiant du patient sur le dispositif de test.

ES Abra la bolsa de papel aluminio y busque los siguientes elementos:

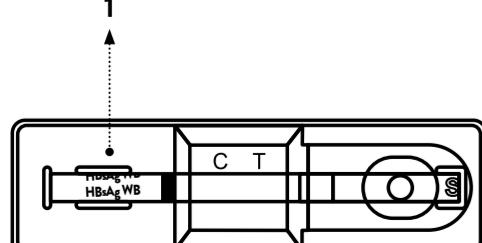
1. Dispositivo de prueba
2. Desecante

Luego, etiquete el dispositivo de prueba con un identificador del paciente.

PT Abra a bolsa de folha de alumínio e procure os seguintes:

1. Dispositivo de teste
2. Dessecante

Em seguida, coloque uma etiqueta no dispositivo com o identificador do paciente.



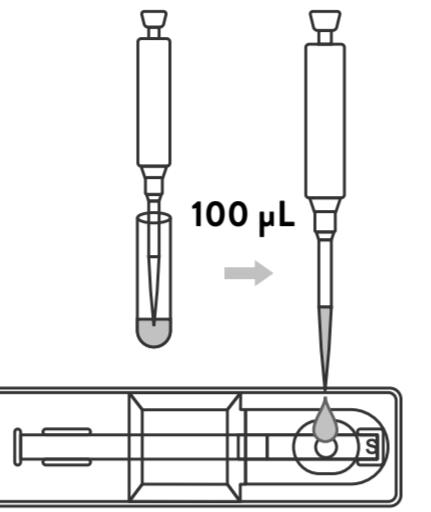
Specimen collection / Prélèvement de l'échantillon / Obtención de la muestra / Colheita de amostras

1 **EN** Take 100 µl of serum, plasma or whole blood specimen using a micropipette. Dispense 100 µl of serum, plasma or whole blood specimen into the specimen well "S".

FR Prélever 100 µl d'échantillon de sérum, de plasma ou de sang total à l'aide d'une micropipette. Déposer 100 µl d'échantillon de sérum, de plasma ou de sang total dans le puits d'échantillon « S ».

ES Con una micropipeta, tome 100 µl de la muestra de suero, plasma o sangre. Instile 100 µl de la muestra de suero, plasma o sangre en el espacio para muestras "S".

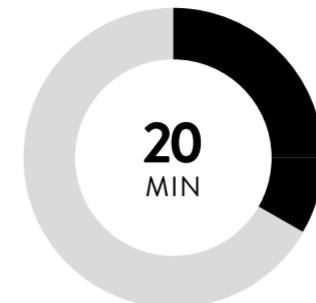
PT Tire 100 µL de amostra de soro, plasma ou de sangue total com uma micropipeta. Deite 100 µL de amostra de soro, plasma ou sangue total no poço da amostra "S".

2 **EN** Interpret test results at 20 minutes. Do not read test results after 20 minutes; late readings can yield false results.

FR Interpréter les résultats du test au bout de 20 minutes. Ne pas lire les résultats du test au-delà de 20 minutes, car il est alors possible qu'ils soient erronés.

ES Una vez transcurridos 20 minutos, interprete los resultados. No lea los resultados después de 20 minutos; una lectura tardía puede arrojar resultados falsos.

PT Interprete os resultados do teste após 20 minutos. Não leia os resultados do teste após 20 minutos; as leituras tardias podem gerar resultados falsos.



INTERPRETATION / INTERPRÉTATION / INTERPRETACIÓN / INTERPRETAÇÃO

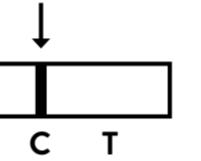
NON-REACTIVE / NON RÉACTIF / NO REACTIVO / NÃO REATIVO

EN The presence of only the control line (C) within the result window indicates a non-reactive result.

FR La présence de la ligne de contrôle uniquement (C) dans la fenêtre de résultat indique un résultat non réactif.

ES Si solo aparece la línea de control (C) en la ventana de resultados, el resultado es no reactivo.

PT A presença apenas da linha de controlo (C) dentro da janela de resultados indica um resultado não reativo.



REACTIVE / RÉACTIF / REACTIVO / REATIVO

EN The presence of the test line (T) and the control line (C) within the result window, regardless of which line appears first, indicates a reactive result.

FR La présence de la ligne de test (T) et de la ligne de contrôle (C) dans la fenêtre de résultat, quelle que soit la ligne apparue en premier, indique un résultat réactif.

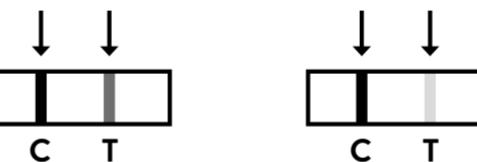
ES ▲ Attention : si la ligne de test est présente, même très pâle, le résultat est considéré comme réactif.

PT ▲ Attenção : a presença de qualquer linha de teste, mesmo sendo muito tênue, significa que o resultado é considerado reativo.

FR ▲ Attention : si la ligne de test est présente, même très pâle, le résultat est considéré comme réactif.

ES ▲ Precaución : La presencia de cualquier línea de prueba, aunque sea de un color débil, indica que el resultado es reativo.

PT ▲ Atenção : A presença de qualquer linha de teste, mesmo sendo muito tênue, significa que o resultado é considerado reativo.



INVALID / NON VALIDE / NO VÁLIDO / INVÁLIDA

EN If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Instructions may not have been followed correctly or the test kit may have deteriorated. It is recommended that the specimen be retested using a new test device.

FR Si la ligne de contrôle (C) n'est pas visible dans la fenêtre de résultat après la réalisation du test, le résultat est considéré comme non valide. Il se peut que les instructions n'aient pas été suivies correctement ou que le kit de test se soit détérioré. Il est recommandé d'analyser à nouveau l'échantillon à l'aide d'un nouveau dispositif de test.

ES Si no se ve la línea de control (C) en la ventana de resultados después de ejecutar la prueba, se considera que no hay un resultado válido. Esta situación puede deberse a que no se siguieron correctamente las instrucciones o a que el kit de prueba se haya deteriorado. Recomienda-se que la muestra sea nuevamente probada utilizando un nuevo dispositivo de prueba.

PT Se a linha de controlo (C) não estiver visível dentro da janela de resultados após a realização do teste, o resultado é considerado inválido. As instruções podem não ter sido seguidas corretamente ou o kit de teste pode ter-se deteriorado. Recomenda-se que a amostra seja novamente testada utilizando um novo dispositivo de teste.



Glossary of symbols / Glossaire des symboles / Glosario de símbolos / Glossário de símbolos

	Lot Number No. de lot Número de lote Número de lote		Manufacturer Fabricant Fabricante Fabricante
	For in vitro diagnostic use only Pour diagnostic in vitro uniquement Solo para uso de diagnóstico in vitro Somente para uso de diagnóstico in vitro		Catalog Number Code produit Número de Referencia Número de Catálogo
	Do not reuse Usage unique No Reutilizar Não reutilizar		Instructions for use Attention, voir mode d'emploi Atención, ver Instrucciones de uso Atenção, ver Instruções de uso
	Keep away from sunlight Conserver à l'abri de la lumière du soleil Manténgase fuera de la luz del sol Manter afastado da luz solar		Date of manufacture Date de fabrication Fecha de fabricación Data de fabricação
	Keep dry Conserver au sec Manténgase seco Conservar seco		Use By Date de péremption Fecha de caducidad Utilizar até
	Contains sufficient for <>> tests Permet de réaliser <>> tests Contenido suficiente para <>> pruebas Contém o suficiente para <>> testes		Caution Mise en garde Precaución Atenção
	Do not use if package is damaged Ne pas utiliser si l'emballage est endommagé No utilizar si el envase está dañado Não utilizar se a embalagem estiver danificada		Biological Risks Risques biologiques Riesgos biológicos Riscos biológicos