REF 7D2946/7D2947

Determine™ HBsAg 2

Key to symbols used/
Legende der verwendeten Symbole/
Clave de los símbolos utilizados/
Légende des symboles utilisés/
Legenda dei simboli utilizzati/
Designação dos símbolos utilizados

2°C – 30°C Store at 2-30°C/ Bei 2-30°C lagern/ Guardar a temperaturas entre 2 y 30°C/ Conserver entre 2-30°C/ Conservare a 2-30°C/ Armazenar entre 2-30°C

REF Catalogue Number / Katalognummer/ Número de catálogo/ Référence catalogue/ Numero di catalogo/ N° de Catálogo

Do not use if package is damaged/ Bei beschädigter Verpackung nicht verwenden/ No utilizar si el envase está roto/ Ne pas utiliser si l'emballage est endommagé/ Non utilizzare se la confezione è danneggiata/ Não utilizar caso a embalagem esteja danificada

Do not reuse/ Nicht wiederverwenden/ No reutilizar/ Ne pas réutiliser/ Non riutilizzare/ Não reutilizar

Keep away from sunlight/ Vor Sonnenlicht geschützt aufbewahren/ No exponer a la luz solar/ Conserver à l'abri de la lumière du soleil/ Tenere lontano dalla luce solare/ Manter afastado da luz solar

IVD *In Vitro* Diagnostic Medical Device/ Medizinprodukt für die *In Vitro*-Diagnostik/ Dispositivo de diagnóstico médico *in vitro*/ Dispositif médical de diagnostic *In Vitro*/ Dispositivo medico diagnostico *in vitro*/ Dispositivo Médico para Diagnóstico In Vitro

Σ 20 Contains Sufficient for 20 tests/ Enthält eine ausreichende Menge für 20 Tests/ Contiene material suficiente para realizar 20 pruebas/ Permet de réaliser 20 tests/ Contiene il necessario per 20 test/ Contém o suficiente para 20 testes

Σ 100 Contains Sufficient for 100 tests/ Enthält eine ausreichende Menge für 100 Tests/ Contiene material suficiente para realizar 100 pruebas/ Permet de réaliser 100 tests/ Contiene il necessario per 100 test/ Contém o suficiente para 100 testes

Consult instructions for use/ Lesen Sie vor der Verwendung das Merkblatt/ Consulter les instructions d'utilisation/ Consulte las instrucciones de uso/ Consultare le istruzioni per l'uso/ Consultar as instruções de utilização

EDTA CAPILLARY TUBES EDTA Capillary Tubes/ EDTA-Kapillarröhrchen/ Tubos capilares EDTA/ Tubes capillaires avec EDTA/ Tubi capillari con EDTA/ Tubos Capilares EDTA

CHASE BUFFER Chase Buffer/ Laufpuffer/ Buffer de detección/ Tampon de migration/ Tampone chase (tampone di spinta)/ Tampão de detecção

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4. Clinical and Laboratory Standards Institute, *Clinical Laboratory Waste Management*: Approved Guideline-Third Edition, GP05-A3. January 2011
5. EPA Guide for Infections Waste Management: Publication No. EPA/530-SW-86-014. Washington, DC: US Environmental Protection Agency, 1986:1-1-5, R1-R3, A1-A24.

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Whole Blood / Vollblut / Sangre Total / Sang Total / Sangue Intero / Sangue Total

Pipette
Pipette
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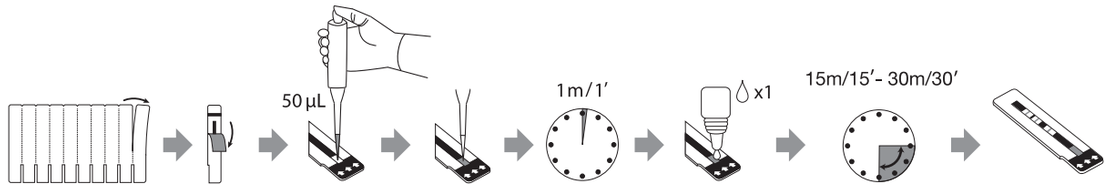
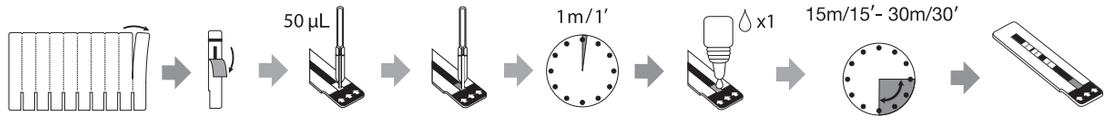
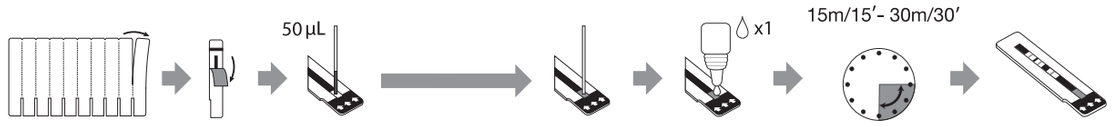


MICROSAFE® Tube
MICROSAFE®-Röhrchen
Tubo MICROSAFE®
TUBE MICROSAFE®
TUBO MICROSAFE®
Tubo MICROSAFE®



EDTA Capillary Tubes
EDTA-Kapillarröhrchen
Tubos capilares EDTA
Tubes capillaires avec EDTA
Tubi capillari con EDTA
Tubos Capilares EDTA



Serum, Plasma / Serum, Plasma / Suero, Plasma / Sérum, Plasma / Siero, Plasma / Soro, Plasma

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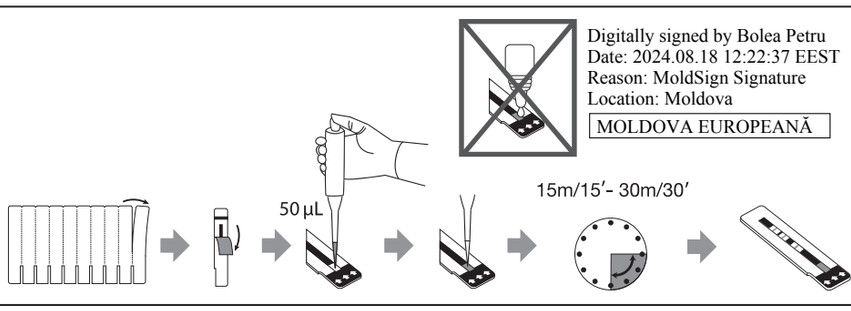

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Location: Moldova
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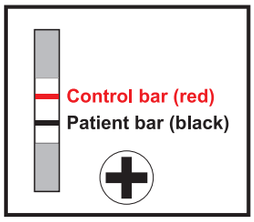
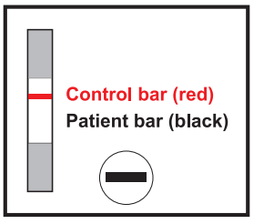
Reactive/Reaktiv/Reactivo/ Réactif/Reattivo/Reativo



Non-Reactive/Nicht-reaktiv No Reactivo/ Non Réactif Non Reattivo/Não Reativo



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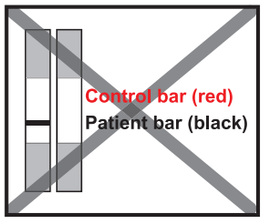

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EN

This instruction for use must be read carefully prior to use. All procedures must be followed accordingly. Reliability of assay results cannot be guaranteed if there are deviations from the instructions in this IFU.

NAME AND INTENDED USE

Determine™ HBsAg 2 is an *in vitro*, visually read, qualitative immunoassay for the detection of Hepatitis B Surface Antigen (HBsAg) in human serum, plasma or whole blood. The test is intended as an aid to detect HBsAg from infected individuals. The test is professional use only. Determine HBsAg 2 is not intended for use in screening blood, plasma, cell or tissue donors.

SUMMARY AND EXPLANATION OF THE TEST

Hepatitis B virus (HBV), is a DNA virus transmitted percutaneously, sexually and perinatally. Worldwide it causes deaths from cirrhosis, liver failure and hepatocellular carcinoma[1]. HBsAg seropositivity is the first serological marker to appear in acute HBV infection[2].

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

Determine™ HBsAg 2 is an immunochromatographic test for the qualitative detection of Hepatitis B Surface Antigen (HBsAg).

A specimen is added to the sample pad. The specimen mixes with biotinylated anti-HBsAg antibodies and black particles coated with anti-HBsAg antibodies. This mixture migrates along the solid phase to the immobilized avidin at the patient bar.

If HBsAg is present in the specimen, the antigen binds to the biotinylated anti-HBsAg antibodies and the black particles coated with anti-HBsAg antibodies. This complex binds to the immobilized avidin forming a black bar on the test strip. If HBsAg is not present, black particles flow past the patient bar and no black bar is formed on the test strip.

To ensure assay validity, a procedural control bar is incorporated in the assay device on the test strip. The red control bar will appear.

CONTENTS

Determine™ HBsAg 2 Test Cards: 2 or 10 cards (containing 10 tests/card), sufficient to perform 20 tests (7D2946) or 100 tests (7D2947)

ACCESSORIES (required)

For testing Whole Blood Samples

CHASE BUFFER (7D2243) 1 Bottle (2.5 mL) containing phosphate buffered saline, preservative and antimicrobial agent

For testing Whole Blood Samples (fingerstick assay)

Lancet

EDTA CAPILLARY TUBES (7D2227)

Microsafe® Tube (SAFE-TEC® Clinical Products, YY1050 (2000 tubes), YY1050100 (100 tubes))

Materials Required But Not Provided

- Disposable gloves
- Timing device
- Micropipette capable of delivering 50 µL (not required for fingerstick method)
- Alcohol swab, gauze pad

WARNING AND PRECAUTIONS

For *In Vitro* Diagnostic Use.

Use the Chase Buffer bottle with attention to avoid contamination of the nozzle. Don't touch nozzle to the sample or sample pad.

Safety data sheet available for professional users on request.

CAUTION:

When handling specimens and reagents, use appropriate biosafety practices[4,5]. These precautions include, but are not limited to the following:

- Wear gloves.
- Do not pipette by mouth.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.
- Clean and disinfect all spills of specimens or reagents using suitable disinfectant, such as 0.5% sodium hypochlorite[3,4].
- Decontaminate and dispose of all specimens, used test strips, and other potentially contaminated materials in accordance with local regulations[3,4].

STORAGE

Store Determine™ HBsAg 2 Test Cards and Chase Buffer at 2-30°C until expiration date.

- When handled and stored as directed, kit components are stable until expiration date. Do not use kit components beyond expiration date.
- Immediately reseal all unused tests in the foil pouch containing the desiccant by pressing seal from end to end to close.
- Do not use wet devices or damaged packages.

SPECIMEN COLLECTION

Serum, Plasma, and Whole Blood Collection by Venipuncture

Use EDTA collection tubes for whole blood and plasma specimens.

- Collect human whole blood by aseptic venipuncture.
- To obtain serum, separate from the clot. To obtain plasma, separate from the packed cells. Separate specimens as soon as possible to avoid any hemolysis.

Whole Blood Collection by fingerstick[4] (See Fig.1)

Use EDTA CAPILLARY TUBES (7D2227) or Microsafe® Tube

CAUTION: Glass capillaries may be damaged during transportation or when in use. Handle with care in order to avoid injury when removing from the package as well as during use and during disposal.

Fig.1

EDTA CAPILLARY TUBES

Before collecting a fingerstick specimen, place a capillary tube on a clean dry surface.

1. Choose the fingertip of the middle, ring, or index finger (whichever is the least callused). Warm the hand as needed with a warm, moist towel or warm water to increase blood flow.
2. Clean fingertip with alcohol; allow to air dry.
3. Position the hand palm-side up. Place the lancet off-center on the fingertip. Firmly press the lancet against the finger and puncture the skin. Dispose the lancet in an appropriate biohazard sharps container.
4. Wipe away the first drop of blood with a sterile gauze pad.
5. Hold the finger lower than the elbow and apply gentle, intermittent pressure to the base of the punctured finger several times.
6. Touch the tip of the capillary tube to the drop of blood. Avoid air bubbles. Fill the tube with whole blood up to between the two marked lines (50 µL).

* If Microsafe® Tube is used, refer to Microsafe® Tube package insert for additional information.

SPECIMEN STORAGE

- Store serum and plasma specimens at 2-8°C and run the test within 7 days of collection. If testing is delayed more than 7 days, the specimens should be frozen (-20°C or colder).
- Avoid repeated freeze/thaw cycles.
- If serum or plasma specimens show particulate matter or turbidity, centrifuge at 10,000g for 5 min at room temperature before sampling. Carefully take the 50 µL test sample from the supernatant. If a lipid layer is formed on the surface of the liquid, ensure that the sample is taken from the clear liquid below that layer.
- For whole blood collected by venipuncture, store at 2-8°C. Do not freeze whole blood specimens. Run the test within 2 days (48 hours) of collection. Mix the specimen well by gentle inversion of the tube immediately before testing.
- For whole blood collected by fingerstick, test immediately.

TEST PROCEDURE

This test should be performed at 18 to 40°C.

1. Remove the desired number of test strips from the 10-test card by bending and tearing at the perforation.
   - To preserve the lot number which appears on the left side of the test card, remove individual test strips starting from the right side of the test card. The lot number and expiry date are not printed on the individual test strips.
2. Remove the protective foil cover from each test.
   - After removing the protective foil cover from each test strip, start the assay within 2 hours.
3. For serum or plasma samples:
   a. Apply 50 µL of sample (precision pipette) to the sample pad (marked by the arrow symbol).
   b. Wait a minimum of 15 minutes (30 minutes maximum) from addition of the sample and read result.

   For whole blood (venipuncture) samples and for whole blood (fingerstick) samples using a Microsafe® Tube:
   a. Apply 50 µL of sample (precision pipette) to the middle of the sample pad (marked by the arrow symbol).
   b. Wait one minute to allow the sample to be absorbed, and then apply one drop of Chase Buffer to the sample pad, holding the bottle vertically.
   c. Wait a minimum of 15 minutes (30 minutes maximum) from addition of the sample and read result.

   For whole blood (fingerstick) samples using EDTA capillary tubes:
   a. Place the capillary tube containing the blood sample to the middle of the sample pad (marked by the arrow symbol) at an upright (vertical) position.
   b. Wait until all the blood is transferred from the capillary tube to the sample pad. Then immediately apply one drop of Chase Buffer to the sample pad, holding the bottle vertically.
      Caution: do not lift the capillary tube from the sample pad before all the blood has been transferred – a bubble may form which will prevent the complete transfer of sample and invalidate the test. It may take more than one minute for full transfer of the sample.
   c. Dispose the used capillary tube as biohazardous material according to local regulations.
   d. Wait a minimum of 15 minutes (30 minutes maximum) from addition of the sample and read result.

NOTE:

- If the test strip dries during reading and it becomes difficult to see the bars, repeat the test using a new test strip and read after 15 minutes. The test strip dries at 30 minutes at 40°C 40% RH.
- If serum or plasma sample does not flow or shows abnormal flow, such as stopping in the middle of the window, centrifuge the specimen and repeat the test with a new test strip.

QUALITY CONTROL

To ensure assay validity, a procedural control system is incorporated in the device. This red control bar will appear in the window. If the control bar does not appear by assay completion, the test result is invalid. Repeat the test using a new test strip.

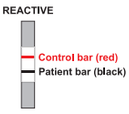
INTERPRETATION OF RESULTS (See pictures)

NOTE:

- Interpret any visible bar (even very faint) in the window as a valid result.
- The test result is valid even if the patient bar appears lighter or darker than the control bar. Any bar, no matter how faint, is interpreted as reactive.
- Even if the color of control bar is dark red, it is valid.
- A test which gives very high background should be considered invalid.
- If an invalid result occurs repeatedly, or for technical assistance, contact your local distributor or call the Advice Line.
- When a whole blood venipuncture or whole blood fingerstick result is reactive with Determine™ HBsAg 2, the result should be confirmed with a plasma or serum test on Determine™ HBsAg 2.

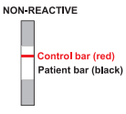
Reactive (Two bars: Red bar and Black bar)

Two bars: one red bar and one black bar appear in the window. The red bar corresponds to control bar and the black bar corresponds to patient bar, respectively.



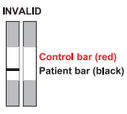
Non-reactive (One bar: Red bar)

One red bar appears and no black bar appears in the window.



INVALID (No bar or One bar: Black bar)

If there is no red control bar in the window, and even if a black patient bar appears in the window, the result is invalid. Repeat the test using a new test strip.



LIMITATIONS OF THE PROCEDURES

- The Determine™ HBsAg 2 test is designed to detect Hepatitis B Surface Antigen (HBsAg) in human serum, plasma and whole blood. Other body fluids or pooled specimens may not give accurate results and should not be used.
- The intensity of the patient bar does not necessarily correlate with the titer of antigen in the specimen.
- No test provides absolute assurance that a sample does not contain low levels of HBsAg such as those present at a very early stage of infection.
- A non-reactive result at any time does not preclude the possibility of exposure to or infection with hepatitis B virus.
- The use of anticoagulants other than EDTA for whole blood or plasma specimens has not been validated for use with the Determine™ HBsAg 2 and may give incorrect results.
- For diagnostic purposes and to differentiate acute HBV infection from chronic HBV infection, the detection of HBsAg must be correlated with patient symptoms and other hepatitis B viral serological markers.
- Biotin treatment higher than 5mg per day may lead to decreased patient bar intensity. Biotin concentrations up to 50 ng/mL in serum or plasma did not impact the sensitivity.

PERFORMANCE CHARACTERISTICS

Sensitivity

Sensitivity was evaluated by testing confirmed HBsAg positive specimens, commercial seroconversion panels, HBV genotype and serotype panels.

1. HBsAg Positive Specimens

A total of 437 confirmed HBsAg positive specimens were tested with Determine HBsAg 2 and a commercially available rapid HBsAg test (Table I). The sensitivity (95% CI) of Determine™ HBsAg 2 on this population of specimens was calculated to be 98.4% (96.7-99.4%). The non-reactive specimens with Determine™ HBsAg 2 were 0.06, 0.06, 0.09, 0.10, 0.13, 0.33 and 1.29 IU/mL by a quantitative HBsAg test kit.

Table I: HBsAg Positive Specimens

Types	Number of Specimens tested	Reactive by Determine™ HBsAg 2	Reactive by alternative rapid HBsAg test
HBsAg positive specimens	369	362	294
HBV genotype determined specimens*	51	51	43
HBsAg serotype determined specimens**	17	17	17
Total	437	430	354
Sensitivity (95% CI)		98.4% (96.7-99.4%)	81.0% (77.0-84.6%)

*Genotypes: A, B, C, D, E, F, G, H, A/E, A/F, D/E, D/F and D/G

**Serotypes: adw2, adr, ayw2, ayw3 and ayw4

2. HBV seroconversion panels

The sensitivity of Determine™ HBsAg 2 was evaluated using 32 sets of seroconversion panels; each including early seroconversion panel members. The results were compared with the results of a commercially available rapid immunochromatographic HBsAg test kit and a quantitative HBsAg test kit (Chemiluminescent microparticle immunoassay (CMIA)). On all sets, Determine™ HBsAg 2 detected HBsAg earlier than a rapid immunochromatographic test kit. On 4 of 32 sets, Determine™ HBsAg 2 detected HBsAg earlier than a CMIA kit. Detection of 4 of 32 sets by Determine™ HBsAg 2 was delayed by 1 bleed date when compared to CMIA kit.

The first reactive date followed by continuously reactive results was compared with the first reactive date with the Determine™ HBsAg 2.

3. Analytical sensitivity of HBsAg

The analytical sensitivity of Determine™ HBsAg 2 was evaluated by testing WHO International Standard for HBsAg (NIBSC code 12/226). The results demonstrated that the test could detect a concentration of 0.1 IU/mL HBsAg.

4. HBsAg Mutant Detection

HBsAg mutant susceptibility was evaluated with Determine™ HBsAg 2. A panel consisting of 14 different recombinant HBsAg mutant panels was tested. The mutant panel consisted of following mutations, P120Q, T123A, T126N, T126S, Q129R, Q129H, Q129L, M133H, M133L, K141E, P142S, T143K, D144A and G145R. All 14 samples were detected with Determine™ HBsAg 2.

Specificity

A total of 1650 confirmed negative serum or plasma specimens were tested with the Determine™ HBsAg 2 and the specificity (95% CI) was determined (Table II). The specificity was 99.6% (99.1-99.8%).

Table II: HBsAg Negative Specimens

Population	Number of tested specimens	Determine™ HBsAg 2	Rapid HBsAg Test
		Non-reactive	Non-reactive
Seronegative specimens*	1027	1027	1027
Clinical specimens	213	209	210
Pregnant women	206	205	205
Disease states other than HBV and potentially interfering substances**	204	202	202
Total	1650	1643	1644
Specificity (95% CI)		99.6% (99.1-99.8%)	99.6% (99.2-99.9%)

*Including specimens collected in USA (1240) and Africa (20)

**Rheumatoid factor, antinuclear antibody, systemic lupus erythematosus, high cholesterol, high total protein, high IgM, high IgG, human anti mouse IgG, other infections (Hepatitis A virus, Hepatitis C virus, HTLV I, Cytomegalovirus, Toxoplasma IgG, Syphilis, Herpes simplex virus 1/2 and Epstein-Barr virus), Flu vaccinated patients, non-virus liver disease and dialysis patient specimens

Sample type

All specimen matrices (serum, plasma, whole blood venipuncture and whole blood fingerstick) were tested.

Table III:
HBsAg sensitivity in matched whole blood (venipuncture and fingerstick), serum and plasma specimens

Population	No. of matched specimens tested		Type of Specimens and No. of reactive or non-reactive by Determine™ HBsAg 2			
			Serum	Plasma	Whole blood venipuncture	Whole blood fingerstick**
HBsAg positive	145	Reactive	142	143	141	141
		Non-reactive	3	2	4	4
		Sensitivity	97.9%	98.6%	97.2%	97.2%
HBsAg negative	203	Reactive	1	0	0 (3)	0 (3)
		Non-reactive	202	202*	203	203
		Specificity	99.5%	100%	100% (98.5%)	100% (98.5%)

* There was no plasma result for 1 study subject.

**EDTA capillary tubes were used for 225 specimens. MICROSAFE® Tubes were used for 123 specimens. Prospective multiple (matched) specimens of whole blood, serum and plasma from 348 individuals (145 HBsAg positive) in European countries were tested with Determine™ HBsAg 2 (Table III). Whole blood initially reactive results were adjudicated utilizing the serum or plasma results. The true negative but initially reactive whole blood results are listed in parentheses in Table III.

The results obtained from all specimen matrices showed correlation, except for the following. One positive specimen (0.27 IU/mL) was reactive with plasma but non-reactive with serum, venipuncture whole blood and fingerstick.

One positive specimen (0.14 IU/mL) was reactive with serum and plasma but non-reactive with venipuncture whole blood and fingerstick. One negative specimen was non-reactive with plasma, venipuncture whole blood and fingerstick but reactive with serum. Three negative venipuncture whole blood specimens were reactive. Three negative fingerstick specimens were reactive.

All whole blood true negative but reactive specimens were adjudicated utilizing the serum or plasma results; all were non-reactive on serum and plasma testing; the final assessment is that the samples were non-reactive.

Two seropositive specimens (0.08 IU/ml and 0.14 IU/ml) were non-reactive with all specimen matrices at 15 minutes. At 30 minutes, results for serum and plasma were reactive.

Advice Line (See Front Page)

BIBLIOGRAPHY (See Front Page)

The manufacturing process produces different lot numbers for the kit and test cards; these lot numbers are traceable.