For professional use

Humasis

HBsAg Card

One Step HBsAg Test

Please read the instructions carefully before use!

[INTENDED USE]

Humasis HBsAg Card is one step in vitro diagnostic test based on immunochromatographic assay. It is designed for qualitative determination of Hepatitis B surface antigen(HBsAg) in human serum or plasma specimen.

[SUMMARY AND EXPLANATION]

Most cases of acute viral hepatitis are caused by Hepatitis A virus(HAV), Hepatitis B virus(HBV), or Hepatitis C virus(HCV). HBV alone is estimated to have infected 400 million people throughout the globe, making it one of the most common human pathogens. Hepatocellular carcinoma(HCC), one of the most common cancers afflicting humans, is primarily caused by chronic HBV infection. The complex antigen found on the surface of HBV is called Hepatitis B surface antigen (HBsAg). It is also called Australian antigen previously. Testing for HBsAg in human serum or plasma specimen is extremely important in the diagnosis of HBV infection. HBsAg appears in the patient's blood from 4~12 weeks on average after infection and precedes onset of clinical symptoms of hepatitis. HBsAg has four major subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the determinant, there are several serotypes of Hepatitis B virus.

[PRINCIPLE OF THE TEST]

Humasis HBsAg Card is an immunochromatographic assay for qualitative detection of HBsAg in serum or plasma specimen. A nitrocellulose membrane strip in the device contains a test line pre-coated with anti-HBsAg antibody. When sample is added to sample pad, it moves through the conjugate pad, which contains anti-HBsAg antibody-colloidal gold conjugate. If the sample contains HBsAg, antigen-antibody-colloidal gold complex will be formed. The complex will continue to migrate across the membrane by capillary action and reacts with anti-HBsAg antibody that is coated on the test line. The presence of colored line in the test region indicates a positive result, while its absence indicates a negative result. The sample will continue to move along the membrane until it reaches the control line and produces a second visible line. This control line indicates that the sample has migrated across the membrane as intended and the test was performed properly.

[CONTENTS]

Test devices
Instruction manual

[STORAGE AND SHELF-LIFE]

1. Store the test device packaged in sealed foil pouch at 1~30℃(34~86℉). Do not freeze.
2. Shelf-life : 24 months from manufacturing date.

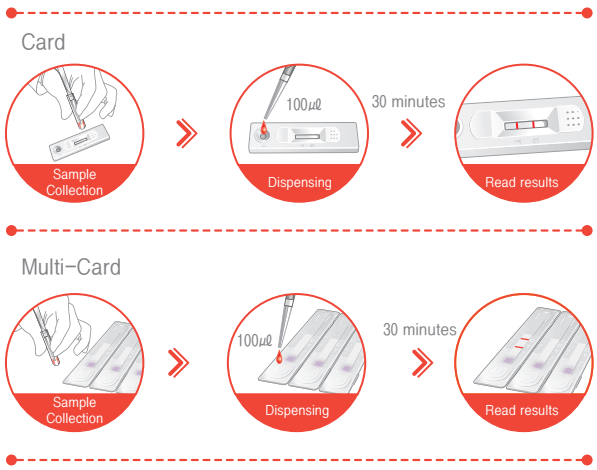
[SPECIMEN COLLECTION AND PREPARATION]

Serum or plasma can be used as specimens.

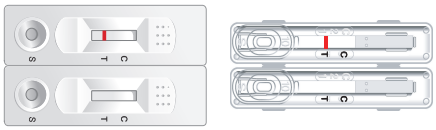
1. When separating the serum or plasma samples, blood cells or blood clotting factors should be completely removed by centrifugation.
2. Specimens with severe hemolysis or suspension, specimens with high blood lipid concentrations or contaminated specimens should be avoided as they can give inaccurate results.
3. Do not use heat-treated specimens or specimens that have been frozen and thawed several times.
4. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens can be refrigerated at around 4℃ for up to 1 day. If the samples must be stored for more than 1 day, they should be frozen below -20℃.
5. If specimens are to be shipped, they should be packed in compliance with federal, state or local regulations for the transportation or etiologic agents.

[TEST PROCEDURE]

1. Bring all materials and specimens to room temperature for 30 minutes before beginning the test. Humidity and temperature can adversely affect results. So, keep sealed until usage, and once opened use immediately.
2. Release the test device from the foil pouch and place it on a clean, dry and level surface.
3. Write the specimen ID on the test device.
4. Holding the pipette vertically, add exactly 100 uL of the sample to the sample well. Be careful not to allow the sample to enter the test result window.
   Note: Use a fresh pipette or tip for each specimen in order to prevent cross-contamination.
5. Read the result within 30 minutes after applying sample. Do not interpret the results after 30 minutes.



[INTERPRETATION OF RESULT]

Result	Example	Interpretation
Negative		If the test region(T) has no colored line and the control region(C) displays a colored line, the result is negative.
Positive		If the test region(T) has a colored line and the control region(C) displays a colored line, the test result is positive.
Invalid		If there is no colored line in the control region(C), the result is invalid.

[QUALITY CONTROL]

In all test results, a colored line should be visible in the control region(C).

[LIMITATIONS OF THE TEST]

- For in vitro diagnostic use only.
- Do not use the test device beyond the expiration date.
- Do not eat, drink or smoke in the area where the specimens and devices are handled.
- Handle all specimens safely as potentially infectious.
- Use disposable gloves when handling potentially infectious specimens and wash hands after handling.
- If the sample is spilled during the test, clean the contaminated area with an appropriate disinfectant such as 1% sodium hypochlorite.
- Dispose of all specimens and materials used in the test after autoclaving at 121℃ for at least 1 hour.
- Do not use the test device if the pouch is damaged or the device is seriously broken.
- Humasis HBsAg Card is intended for the qualitative detection of HBsAg in serum or plasma specimen. It does not completely exclude the possibility of a false positive or a false negative result caused by various factors such as non-specific protein binding or the presences of heterophilic antibodies like human anti-mouse antibodies.
- Humasis HBsAg Card will only indicate the presence of HBsAg in the specimens and should not be used as the sole criteria for the diagnostic of Hepatitis B virus infection.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- Humasis HBsAg Card cannot detect less than 2.38 IU/mL of HBsAg in specimens. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of Hepatitis B virus infection.

[PERFORMANCE CHARACTERISTICS]

● Limit of detection (LoD)

The limit of detection(LoD) of Humasis HBsAg Card is 2.38 IU/mL.

● Cross-reactivity

Cross-reactivity of the Humasis HBsAg Card was evaluated using the negative and low concentrate positive standard solution containing substances shown in the table below. None of the tested cross-reactive substances had any effect on the test performance of the Humasis HBsAg Card.

No.	cross-reactive substances	Concentration
1	ANA Nucleolar positive plasma	1:320 Nuclear
2	CMV IgM positive plasma	3.664 S/CO
3	HAV IgG/Total Ab positive greater than 2 S/CP plasma	14.45 S/CO
4	HIV 1/2 Ab positive plasma	10.563 S/CO
5	HTLV-I Antibody positive plasma confirmed	52.17 S/CO
6	HTLV-II Antibody positive plasma confirmed	2.835 S/CO
7	Mycoplasma IgM Positive plasma	2.243 S/CO
8	Parvo IgM Positive plasma	8.49 S/CO
9	Rubella IgM Positive plasma	2.067 S.CO
10	Rheumatoid factor	4936 IU/mL
11	Toxoplasma IgG Positive plasma	184 IU/mL
12	Pregnancy woman plasma	25 IU/mL

● Interference

Interference of the Humasis HBsAg Card was evaluated using the negative and low concentrate positive standard solution containing substances shown in the table below. None of the tested interfering substances had any effect on the test performance of the Humasis HBsAg Card.

No.	Interfering substances	Concentration	No.	Interfering substances	Concentration
1	Acyclovir	66.6 umol/L	10	Cyanocobalamin	740 pmol/L
2	Albumin	6000 mg/dL	11	Ethanol	86.8 mmol/L
3	Amoxicillin	206 umol/L	12	Glucose	2000 mg/dL
4	Ampicillin	152 umol/L	13	Hemoglobin	1000 mg/dL
5	Ascorbic acid	227 umol/L	14	Ribavirin	1000 mg/dL
6	Bilirubin	500 umol/L	15	Cholesterol	20 mmol/L
7	Chloramphenicol	155 umol/L	16	Heparin	100 U/mL
8	Triglyceride	1000 mg/dL	17	EDTA	5 umol/L
9	Biotin	0.75 mg/mL	18	Sodium citrate	25 g/mL

[CLINICAL EVALUATION]

The clinical evaluation was conducted by testing a total of 220 clinical samples. The following table summarizes the clinical performance of the Humasis HBsAg Card.

Humasis HBsAg Card	Confirmatory method		TOTAL
	POSITIVE	NEGATIVE	
POSITIVE	109	0	109
NEGATIVE	1	110	111
TOTAL	110	110	220

Parameter	Proportion (%)	95% Confidence Interval
Sensitivity	99.1% (109/110)	95%CI: 94.3% ~ 100%
Specificity	100% (110/110)	95%CI: 95.8% ~ 100%

[REFERENCES]

1. Blumberg BS et al., The discovery of Australian antigen and its relation to viral hepatitis. Virol. 1971, 7:223~240.
2. Wei R et al., Solid-phase enzyme immunoassay for hepatitis B sur face antigen. Clin Chem. 1977, 23:813~815.
3. Goodall AH et al., Monoclonal antibodies in a solid-phase radiometric assay for HBsAg Med Lab Sci. 1981, 38:349~354.
4. U.S. Department of Health and Human Services, Biosafety in microbilogical and biomedical laboratories. HHS Publication(NIH) 88-8395. Washington: US Government Printing Office, 1988.
5. Swenson PD et al., Hepatitis viruses. Manual of Clinical Microbiology (American Society of Microbiology). 1991, 959~983.

REF ABSG-7025

REF ABSG-6100

IVD : For *in vitro* diagnostic use

LOT : Lot number

REF : Catalogue number

: Consult instructions for use

: Store at 1~30℃

: Do not reuse

: Manufactured by

EXP : Use by / Expiry date

Humasis Co., Ltd.
Rm. 114, 502, 504, 604, 604-1, B03-01, B03-02,
88, Jeonpa-ro, Dongan-gu, Anyang-si,
Gyeonggi-do, 14042, Republic of Korea
TEL:+82-31-8085-6200, FAX:+82-31-8085-6249
Email:question@humasis.com www.humasis.com

Rev. 04/2022-11-22
SA / PI-2053HU01E