
















SBio HCV Screen Test

Rapid test for detection of antibodies to HCV in human serum

REF	91201025
▽	25 T

 Store at 4 to 30 °C	 Manufacturer	 Batch Number	 Test device	 Do not reuse	 Xn Nan, R22 S23-46-61 Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
 Use by (Last day of stated month)	 Consult Instructions for use	 <i>In vitro</i> Diagnostic Medical Device	 Disposable plastic dropper	 HCV	
 Date of Manufacture	 Catalogue Number	 Contains sufficient for n- tests	 This side up	Rapid test for detection of antibodies to HCV in human serum	

INTRODUCTION

SBio HCV Screen Test is an *in vitro*, rapid, qualitative immunoassay used for the detection of antibodies to HCV virus in human serum. For Professional use.

SUMMARY

Hepatitis C virus (HCV) is a single stranded RNA virus of the Flaviviridae family. HCV is now known to be the causative agent for most, if not all non A, non B hepatitis (NANBH). Antibodies to the hepatitis C encoded antigens are prevalent in the sera of HCV infected individuals. Detection of these antibodies indicates exposure to the Hepatitis C virus.

PRINCIPLE

The membrane of SBio HCV Screen Test is striped with recombinant HCV antigens representing Core, NS3, NS4, NS5 and a reagent control. Specimen is added followed by sample running buffer and allowed to move along the membrane. The IgG present in the sample binds to Protein-A coated on the colloidal gold forming an IgG-Protein A-gold complex. This complex moves along the membrane and gets captured by the HCV specific antigens coated on the membrane forming a red/purple coloured band. The unbound material moves to the other end of the membrane where control reagent captures the complex forming the control band.

REAGENTS AND MATERIALS SUPPLIED

Kit Components

SBio HCV Screen Test kit has following components.

1. Device: Stripped with HCV specific antigens and control reagent along with Protein-A-gold conjugate. Individually pouched.
2. Sample Running Buffer: Buffer containing surfactant and preservatives. Ready to use.
3. Package insert.

MATERIALS REQUIRED BUT NOT SUPPLIED

Micropipette, Timer.

STORAGE AND STABILITY

The sealed pouches in the test kit and the sample running buffer may be stored between 4°C to 30°C for the duration of the shelf life as indicated on the pouch and the vial. After first opening of the sample running buffer vial, the buffer is stable until the expiry date, if kept at 4°C to 30°C. Once the pouch is opened, device must be used immediately. Do not freeze the kit or components.

PRECAUTIONS

1. For *in vitro* diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Do not reuse the test device.
4. Read the instructions carefully before performing the test.
5. Handle all specimens as potentially infectious
6. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
7. Sample running buffer contains sodium azide (0.1%). Avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing

and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build up in the plumbing.

8. If the pouch of the test device is damaged, discard the device and take a new one for the test.

SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum is preferable, specimens may be stored at 2° C to 8° C for up to 7 days, in case of delay in testing. Care should be taken to avoid contamination. Do not use contaminated, turbid, lipemic and haemolysed specimen.

Precautions under the HCV regulations:

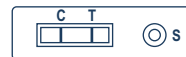
1. For professional use only, not to be used by the general public.
2. Negative result may not have detected recently acquired HCV infection.
3. The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request of registered medical practitioner.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring all reagents and specimen to room temperature before use.
2. Take out required number of devices and label them.
3. Add 5 µl of serum in the sample port marked "S".
4. Add two drops of sample running buffer in the same port. Allow first drop to soak in then add the second drop.
5. Read results at the end of 15 minutes.



Negative: Only one colored band appears on the control region 'C'.



Positive: In addition to the control band, a distinct colored band also appears on the test region "T".

6. The test should be considered invalid if the control band does not appear. Repeat the test with a new device. In the absence of sample addition, control band does not appear.
7. Although, depending on the concentration of antibodies to HCV in the specimen, positive results may start appearing as early as 2 minutes, negative results must be confirmed only at the end of fifteen minutes.
8. In case of a doubtful results at 15 minutes, the test may be extended up to, but no longer than 30 minutes to get a clear background.

REMARKS

To control the proper test performance, it is recommended to include internal control samples.

TEST PERFORMANCE

1. Diagnostic specificity:

A total of 1000 samples were tested with the SBio HCV Screen Test at European Blood Transfusion Centre, 2 samples were found repeatedly positive. The diagnostic specificity is determined as 99.80%.

Centre	Number of samples tested	SBio HCV Screen Test	
		Negative	Positive
A	1000	998	2
Total	1000	998	2

2. Diagnostic sensitivity:

402 HCV positive samples (genotypes 1 to 5) were tested with the SBio HCV Screen Test, all of them were found positive. The diagnostic sensitivity is determined as 100%.

	Number of samples tested	SBio HCV Screen Test	
		Negative	Positive
HCV	402	0	402

3. Possible interferences:

The table below shows the results of the SBio HCV Screen Test tested on a variety of samples containing possibly interfering substances:

Sample type	Number of samples tested	SBio HCV Screen Test	
		Negative	Positive
Clinical specimen	200	200	0
Pregnant women	200	200	0
Related infections (*)	100	100	0

(*) The results were negative for samples containing HBs Ag (20), anti-HIV (4), anti-HTLV (15), anti-HBsAg (18), anti-Rubella (10), anti-parvovirus B19 (17), anti-HAV-IgM(4), anti CMV (12).

4. Seroconversion panels

The sensitivity was evaluated on 30 commercially available seroconversion panels (Boston Biomedica Inc.). It was found that SBio HCV Screen Test was as sensitive as some of the ELISAs assay.

5. Precision

Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of negative and positive HCV samples. No variations were found in the outcome of the different tests.

6. 25 fresh positive serum and/or plasma

Sample type	Number of fresh samples tested	Positive by SBio HCV Screen Test
Same day fresh HCV samples	25	25

LIMITATIONS OF THE TEST

- The test detects the presence of antibodies to HCV in the specimen and hence should not be used as the sole criterion for the diagnosis of HCV infection.
- As with all diagnostic tests, the result must be correlated with clinical findings. If the test result is negative and suspicion still exists, additional follow-up testing using other clinical methods is recommended.
- A negative result at any time does not preclude the possibility of exposure to or infection with HCV.
- A positive test result, even a weak positive, must be confirmed with blot assays such as RIBA.
- It has been observed that SBio HCV Screen Test, like many other immunodiagnostic methods, may show negative result with HIV co-infected or immunodepressed patients. This possibility should be considered while interpreting results.

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