

Core HCV

Rapid test for the detection of antibodies to Hepatitis C Virus (HCV)
in human serum

INTRODUCTION

Core HCV is an in vitro, rapid, qualitative two site sandwich immunoassay used for the detection of antibodies to HCV 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

Core HCV utilizes the principle of lateral flow immunochromatography, a unique two site double antigen sandwich immunoassay on a membrane. As the test specimen flows through the test device, the coloured HCV specific recombinant antigen-colloidal gold conjugate complexes with HCV antibodies in the sample. This complex moves further on the membrane to the test region 'T' where it is immobilized by the HCV specific recombinant antigens coated on the membrane leading to formation of a coloured band, which confirms a positive test result. Absence of this coloured band in the test region indicates a negative test result. The unreacted conjugate and unbound complex, if any, along with rabbit IgG gold conjugate move further on the membrane and are subsequently immobilized by the goat anti-rabbit antibodies coated on the membrane at the control region 'C', forming a coloured band. This control band serves to validate the reagent and assay performance.

REAGENTS AND MATERIALS SUPPLIED

Kit Components

- Core HCV** test device comprises of HCV specific recombinant antigen-colloidal gold conjugate co-dispensed with rabbit IgG colloidal gold conjugate; pre dispensed with HCV specific recombinant antigen at region 'T', and anti rabbit antiserum pre dispensed at the region 'C', along with a plastic sample dropper and desiccant.
- Sample Running Buffer: Phosphate Buffer, 0.15 M, pH 8.0 with 1.5% Tween 20 and 0.1% sodium azide.
- Package insert.

Cat. No./Component	HCV-130001	HCV-130010	HCV-130022	HCV-130050	HCV-130100
Test device	1	10	25	50	100
Sample Running Buffer	1 ml x 1 bottle	5 ml x 1 bottle	10 ml x 1 bottle	10 ml x 2 bottles	10 ml x 4 bottles

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 expiration date, if kept at 4°C to 30°C. Do not freeze the kit or components.

NOTES

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
6. 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.
7. If the colour of the desiccant has turned from blue to white at the time of opening the pouch, another test device must be run.

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 24 hours, in case of delay in testing.

Do not use turbid, lipemic and haemolysed specimens.

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 the kit components to room temperature (20 °C -28 °C) before testing.
2. Open the pouch and remove the device. Once opened, the device must be used immediately.
3. Label the test device with patient's identity.
4. Add two drops of serum (50 µl) using the sample dropper provided, in the well marked "A". A lab micropipette can also be used.
5. Add 3 drops of sample running buffer in the well marked "B" using the dropper vial.
6. At the end of 15 minutes read the results as follows:

NEGATIVE



POSITIVE



Negative: Only one coloured band appears at the control region "C".

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

7. The test should be considered invalid if neither the test band nor the control band appears. Repeat the test with a new device.
8. 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.
9. In case of a doubtful result at 15 minutes, the test may be extended upto, but no longer than, 30 minutes to get a clear background.

REMARK

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

TEST PERFORMANCE

1. Diagnostic specificity:

A total of 1003 samples were tested with the **Core HCV** at European Blood Transfusion Centres. 2 samples were found repeatedly positive .The diagnostic specificity is determined as 99.80%.

Centre	Number of samples tested	Core HCV	
		Negative	Positive
A	1003	1001	2
Total	1003	1001 (99.80%)	2

2. Diagnostic sensitivity:

400 HCV positive samples were tested with **Core HCV**. The diagnostic sensitivity is determined as 98.25% as compared to ELISA methods.

	Number of samples tested	Core HCV	
		Negative	Positive
HCV	400	7*	393

* These samples were PCR negative and indeterminate with Blot-assays, 4 samples are confirmed HIV.

3. Possible Interferences:

The table below shows the results of the **Core HCV** tested on a variety of samples containing possibly interfering substances:

Sample type	Number of samples tested	CoreHCV	
		Negative	Positive
Clinical specimens	212	212	0
Pregnant women	200	200	0
Related infections (*)	107	107	0

(*) The results were negative for samples containing HBsAg (20), anti-HIV (6), anti-HTLV (14), anti-HSV(12),anti –VZV (9), anti- EBV (4), anti-HAV-IgM (15),anti CMV (20),RF (7).

4. Seroconversion panels

The sensitivity was evaluated on 30 commercially available seroconversion panels (Boston Biomedica Inc.). It was found that **Core HCV** was less sensitive than some of the ELISA's.

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.








LIMITATIONS OF THE TEST

1. 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.
2. 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.
3. A negative result at any time does not preclude the possibility of exposure to or infection with HCV.
4. A positive test result, even a weak positive, must be confirmed with blot assays such as RIBA for example.
5. It has been observed that **Core HCV**, 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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SYMBOLS USED ON THE CORE HCV LABELS

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
IVD	In vitro diagnostic medical device
CARD	Test Device
PIPETTE	Disposable Plastic Dropper
BUF	Sample running buffer
	Manufactured By
	Date of Manufacture
	Contains sufficient <n> tests
<p>Xn</p>  R22 - S23-46-61 NaN ₃	R22:Harmful if swallowed; S23:Do not breathe vapour S46:If swallowed, seek medical advice immediately and show this container or label S61:Avoids release to the environment. Refer to special instructions/safety data sheets

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