SYMBOLS USED ON THE

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
I V D	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
Xn  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

Aspect Court, 4 Temple Row
Birmingham B2 5HG
UNITED KINGDOM

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ImmunoFlow HCV

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

CE 0459

INTRODUCTION

ImmunoFlow ™ HCV 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 ImmunoFlow HCV 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.

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REAGENTS AND MATERIALS SUPPLIED

Kit Components

ImmunoFlowHCV 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. Instruction for use

Cat.No./ Component	HCV-120025	HCV-120050	HCV-120100
Test Device	25	50	100
SampleRunning Buffer	5 ml X 1 bottle	5 ml X 2 bottle	5 ml X 4 bottles

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Micropipette 2. 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 expiration 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. 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 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 specimens.

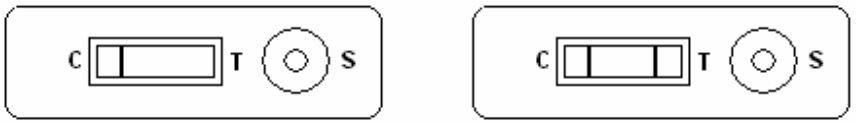
Precautions under the HCV regulations:

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 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: POSITIVE:



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 appears. 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.

REMARK:

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 Immunoflow 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	ImmunoFlow HCV	
		Negative	Positive
A	1000	998	2
Total	1000	998	2

2. **Diagnostic sensitivity:**
402 HCV positive samples (genotypes 1to 5) were tested with the ImmunoFlow HCV, all of them were found positive.
The diagnostic sensitivity is determined as 100%.

	Number of samples tested	ImmunoFlow HCV	
		negative	positive
HCV	402	0	402

3. **Possible Interferences:**
The table below shows the results of the ImmunoFlow HCV tested on a variety of samples containing possibly interfering substances:

Sample type	Number of samples tested	ImmunoFlow HCV	
		negative	positive
clinical specimens	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 ImmunoFlow HCV 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.

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.
5. It has been observed that Immunoflow 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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