

Hepatitis C Virus

NEW
CE 0483

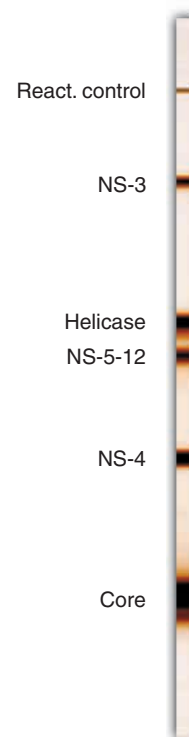
recomBlot HCV IgG 2.0

Immunoblot test with antigens produced by recombinant technique for the detection of IgG antibodies against the hepatitis C virus (HCV)

The most important pathogen responsible for parenterally transmitted non-A, non-B hepatitis is the hepatitis C virus (HCV). This disease is characterized by an incubation period of 2 - 26 weeks and a mild to fulminant course in the acute phase. 50 - 70 % of the patients develop chronic hepatitis which leads to liver cirrhosis in 20 % of the cases. As with hepatitis B, the risk of developing hepatocellular carcinoma is also greatly increased in the case of a chronic HCV infection.

At present, strict indications for the administration of blood products as well as the screening of blood and plasma donors are the most effective measures to prevent a HCV infection.

recomBlot HCV IgG uses recombinant antigens, which are separated by gel electrophoresis and transferred to a nitrocellulose membrane (Western blot). Screening results can be easily and safely confirmed with this test.



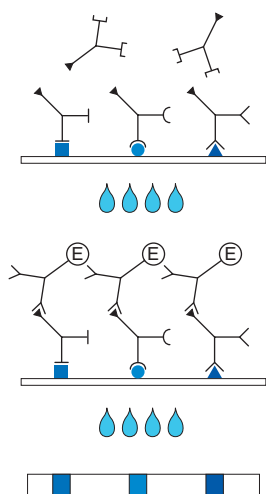
Product Advantages

- **Recombinant antigens**, therefore
 - highest sensitivity, specificity and reproducibility
 - easy and clear interpretation due to easy readable bands
 - use of five serologically relevant HCV antigens
- **True Western Blot** technique
- Serum incubation is limited to **1 hour**
- Save evaluation by cut-off control serum
- Easy evaluation due to **band specific point values**
- Easy test procedure (automation possible)
- **CE certification** by notified body (replace the former PEI accreditation)

Recombinant antigens

Antigen	Recombinant Antigen	Size [kDa]
NS-3	Non-structural protein with helicase / protease activity	70
Helicase	Non-structural protein / part of NS-3 with helicase activity	40
NS-5-12	Non-structural protein / part of NS-5	30
NS-4	Non-structural protein / N-terminal part	27
Core	Virus capsid / structural protein	14

■ Test Principle and Procedure



1st Incubation: A test strip loaded with HCV antigens is incubated with diluted serum or plasma in a dish for **1 hour**.

Wash 3 times

2nd Incubation: Peroxidase conjugated anti-human antibodies (IgG specific) are added. Incubate for **45 minutes**.

Wash 3 times

Color reaction: **5 - 15 minutes** after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips occupied by antibodies.

■ Evaluation

Within the CE certification the *recomBlot* HCV IgG 2.0 was evaluated by testing of 1137 samples from various sera panels. The panels included blood donors, HCV-positive samples (with positive results by screening assays), seroconversions and potentially interfering samples.

For the calculation of sensitivity and specificity of the *recomBlot* HCV IgG 2.0 only clearly determined sera (identified by consistent comparative assays) were used.

<i>recomBlot</i> HCV 2.0	HCV-Status well defined		total
	negative	positive	
negative	605	1*	606
positive	0	300	300
indeterminate	22	1	23
total	627	302	929

*The sample shows weak positive ELISA results, but was consistently negative in confirmation assays. HCV-RNA determination by polymerase chain reaction was tested positive. It must be pointed out that the HCV positive samples also comprised haemodialysis patients. Several publications describe the fact that HCV viraemia can occur without detection of HCV antibodies.

Sensitivity: 99,3%

Specificity: 96,5%

■ Storage and Shelf Life

At 4 °C 12 months from the date of production

■ Commercial Product

Article No. 4302 ***recomBlot* HCV IgG 2.0**
Reagents for 20 determinations