

WHAT DOES "SCORE" STAND FOR?

<u>S</u>hort procedure: Besides the overnight procedure (16 h), a 3-hour sample incubation procedure is available. The overnight incubation requires 10 μ l sample, while the short procedure needs 20 μ l. All other reagents and incubation times are equal.

<u>CO</u>lor coded reagents: avoid mix-ups because Sample Diluent, Conjugate, Substrate, Wash Solution and Stop Solution have a different color code.

REady-to-use reagents: Sample Diluent, Conjugate, Substrate and Stop Solution are ready-to-use.

WHICH VIRAL PROTEINS ARE THE TARGETS OF HUMORAL ANTI-HCV IMMUNE RESPONSE?

Clearly the core, NS3, NS4B and NS5A represent the major antigenic proteins and the INNO-LIA™ HCV Score test is more sensitive in the case of NS3 and E2 proteins [2].

WHY DOES INNO-LIA™ HCV SCORE HAVE TWO CORE ANTIGENS?

The 8 immmunodominant epitope regions of the HCV core region are determined in 2 clusters. The two synthetic peptides (C1 and C2) encompass the two immunodominant epitope clusters.

In order to increase specificity and sensitivity, they are presented in two separate lines. This makes it possible to already detect positive samples which are only reactive on C1 and C2 [1].

[1] Maertens Geert , Dekeyser Filip , Geel Anja , Sablon Erwin , Bosman Fons , Zrein Maan , Pollet Dirk . Confirmation of HCV Antibodies by the Line Immunoassay INNO-LIA HCV Ab III . Methods Mol Med. 1999; 19:11-25.

WHAT IS THE ADDED VALUE OF THE E2 ANTIGEN ON INNO-LIA™ HCV SCORE?

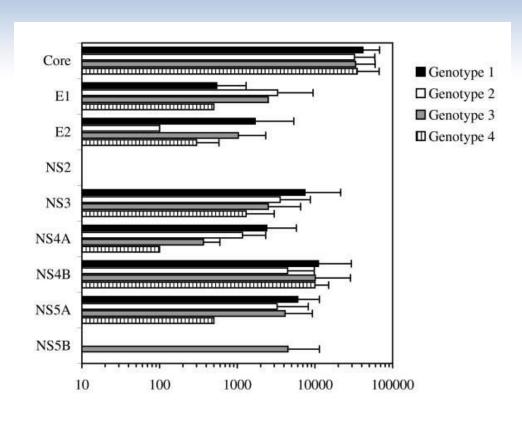
E2 shows a strong relation with RNA positivity, which makes it clinically relevant to detect E2.

In certain cases, E2 makes the difference to detect HCV (for example when E2 is seen together with reactivity only on one core or NS3) [1].

Figure 1 gives an overview of anti-HCV responses in patients infected with different HCV genotypes [2]







Antibody titer

[2] Sillanpää M, Melén K, Porkka P, Fagerlund R, Nevalainen K, Lappalainen M, Julkunen I. Hepatitis C virus core, NS3, NS4B and NS5A are the major immunogenic proteins in humoral immunity in chronic HCV infection. Virol J. 2009 Jun 23; 6:84.

IS INNO-LIA™ HCV SCORE MISSING NS5B ANTIGEN?

No, because INNO-LIA™ HCV Score has the clinically relevant NS5A antigen.

Sillanpäa et al. found that most of the 68 HCV RNA and antibody positive patient sera studied recognized the core, NS3, NS4B and NS5A proteins with high titers.

These results showed that antibody responses to various HCV proteins show considerable qualitative and quantitative differences with the NS3, NS4B and NS5A proteins being highly immunogenic in practically all HCV-infected individuals while certain proteins such as NS2 and NS5B were virtually devoid of all immunogenic activity [2].

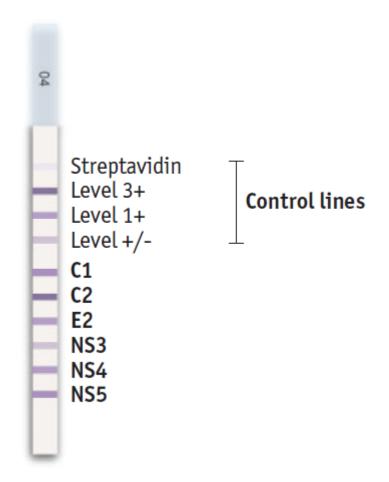




WHAT DOES A 'NORMAL' STRIP LOOK LIKE?

A 'normal' strip shows reactivity on the three control lines: level 3+, 1+ and +/-.

The strip can be interpreted as positive, negative or indeterminate for HCV antibodies.



WHERE IS THE PRODUCT USED?

The INNO-LIA™ HCV Score is used in blood banks, clinical and hospital laboratories.

CAN THE ASSAY BE AUTOMATED?

Yes, Fujirebio Europe N.V. has 2 automation options with different throughput.

- Auto-LIA[™] 48 and Auto-LiPA[™] 48 (48 samples)
- AutoBlot 3000 (H) (20 samples)



FAQ INNO-LIATM HCV Score



The interpretation of the strips can be done by visual analysis (reading card included in the kit) or by the LiRAS $^{\text{TM}}$ for Infectious Diseases interpretation software.

With the LiRAS™ for Infectious Diseases, the interpretation for all infectious diseases INNO-LIA™ Score products (HCV, HIV, Syphilis and HTLV) can be automated.

CAN I RUN DIFFERENT INNO-LIA™ SCORE PRODUCTS TOGETHER?

Yes, the INNO-LIA™ Score reagents are interchangeable except the sample diluent (assures high sensitivity/specificity) but reagents with different lot numbers should not be mixed.

