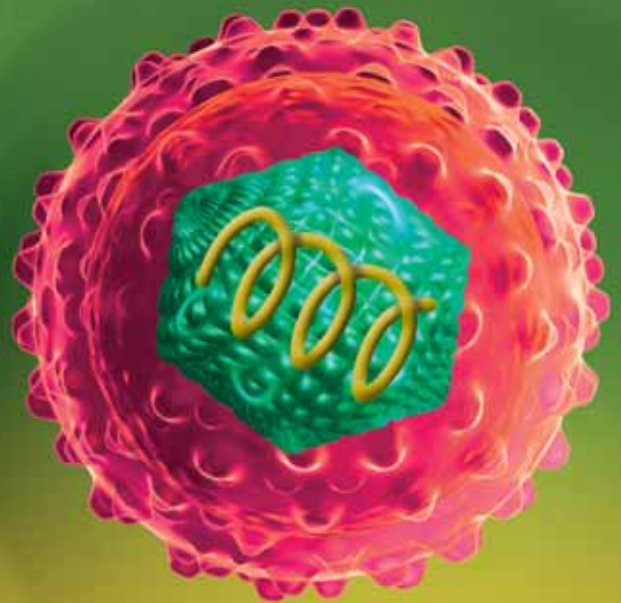


# Hepatitis and Retrovirus

## LIAISON<sup>®</sup> XL **murex** HCV Ab

Accurate diagnosis of the early stage of HCV infection



DiaSorin

The Diagnostic Specialist

FOR OUTSIDE THE US AND CANADA ONLY

# LIAISON® XL **murex** HCV Ab is Your solution

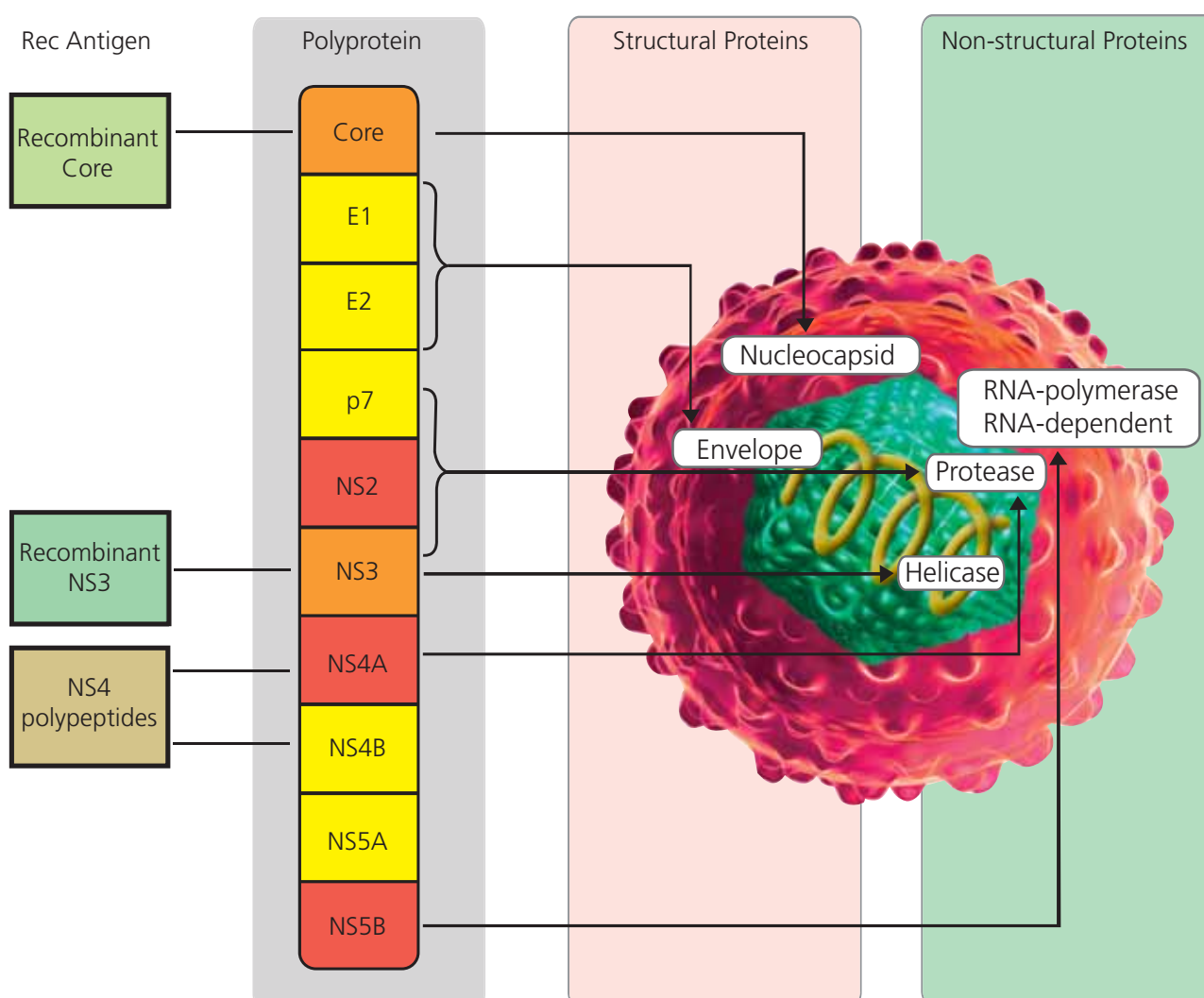
## LIAISON® XL murex HCV Ab main features

The LIAISON® XL murex HCV Ab indirect chemiluminescence assay format ensures reliable data.

- **Unique selection of raw material for reliable results.**
- **Superior sensitivity for early diagnosis.**
- **Detection of all major HCV genotypes.**
- **Exceptional specificity to meet laboratory needs.**
- **High reproducibility for confidence in results.**

**High-quality recombinant antigens** (Core, NS3 and chimeric NS4) specific for HCV. The HCV Core antigen is obtained in baculovirus system and the HCV NS3 and NS4 recombinant antigens are expressed in *E. coli*.

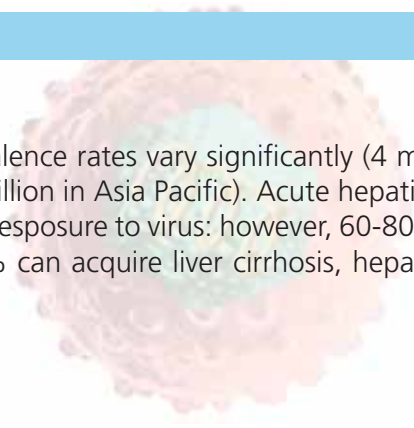
### Hepatitis C Virus Genome



# Early detection? Acute or chronic infection?

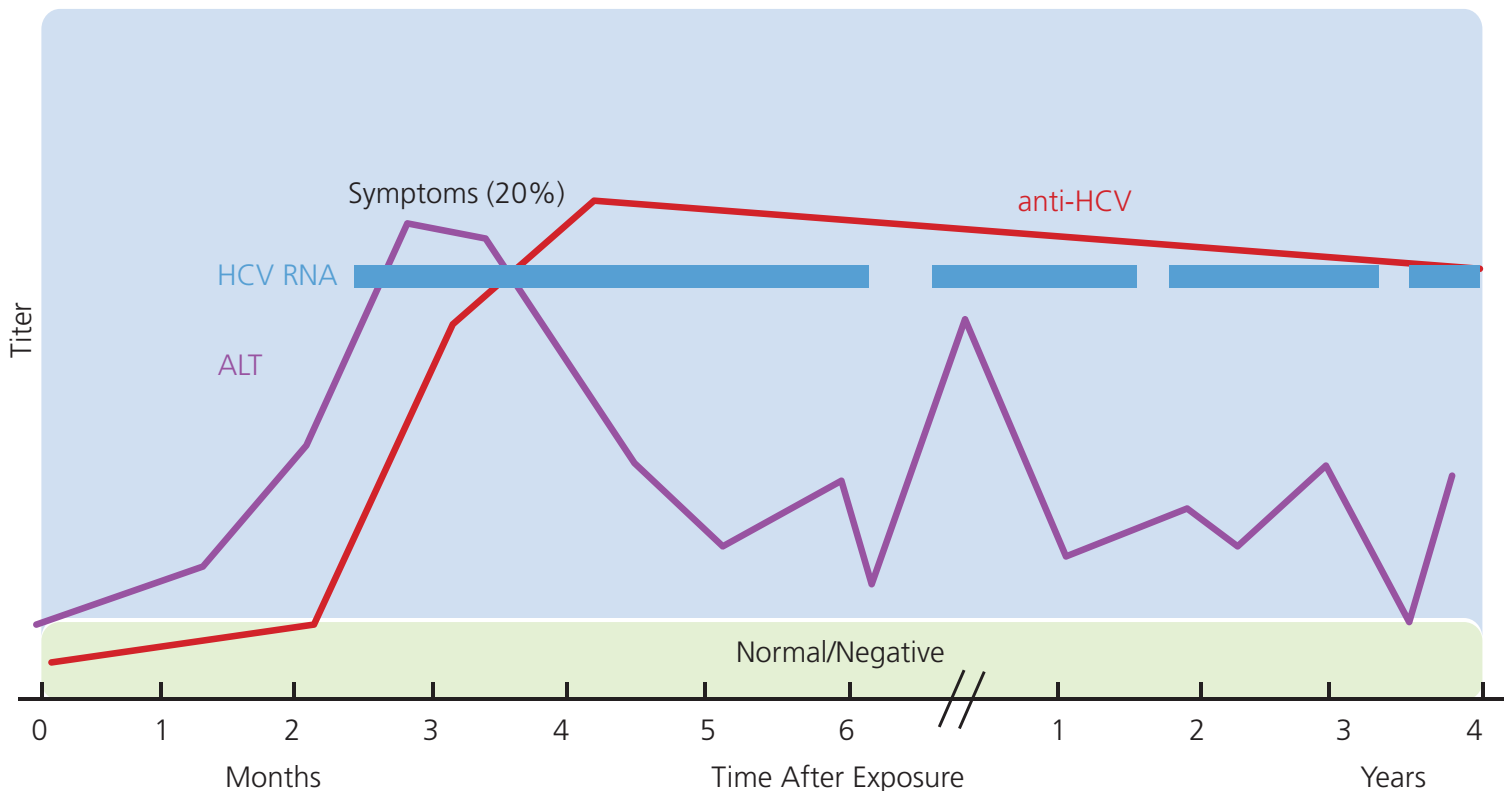
## Hepatitis C

HCV infection afflicts more than 170 million people worldwide, however prevalence rates vary significantly (4 million in North America, 7 million in Latin America, 7 million in Europe and 80 million in Asia Pacific). Acute hepatitis C virus infection is a short-term illness that occurs within the first 6 months after exposure to virus: however, 60-80% of the individuals who contract the disease develop chronic hepatitis and 20% can acquire liver cirrhosis, hepatic failure and increased risk of hepatocellular carcinoma.



### HCV serological pattern: from acute HCV to chronic infection

Acute HCV Progressing to Chronic HCV Infection

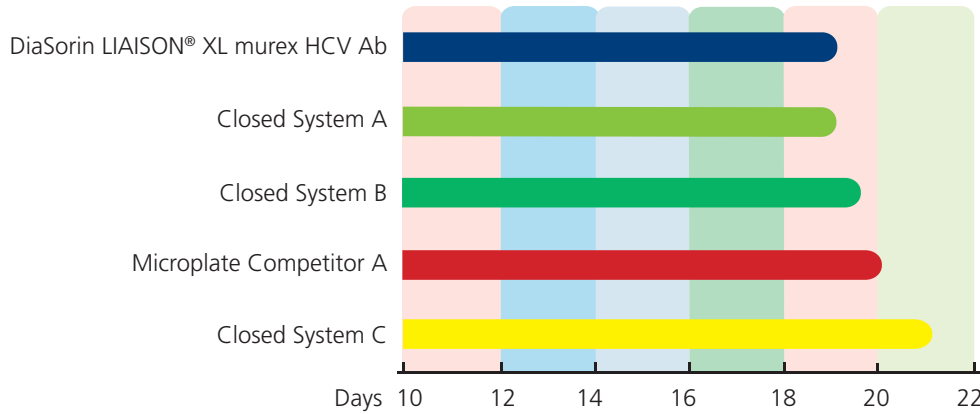


HCV is diagnosed serologically by detecting antibodies specific to the hepatitis C virus (anti-HCV). The serologic window between HCV infection and the detectability of specific antibodies varies from patient to patient and seroconversion occurs on average 7-8 weeks after the onset of infection. Anti-HCV is detectable in 50-70% of patients at the onset of clinical symptoms and later in the remaining patients. In patients with spontaneously resolving infection, anti-HCV may persist throughout life, or decrease slightly while remaining detectable or gradually disappear after several years. Anti-HCV persists indefinitely in patients who develop chronic infection, although antibodies may become undetectable in cases of profound immunodepression.

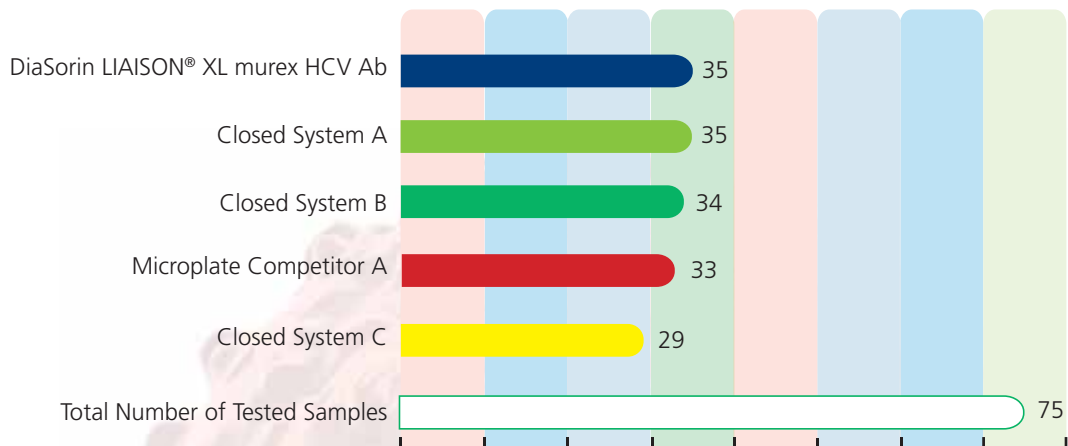
# LIAISON® XL murex HCV Ab...

## Excellent diagnostic sensitivity in the detection of HCV from the early phase of infection

### Seroconversions (n = 11): days of detection for HCV Ab assays



### Total number of detected samples (11 seroconversion panels)



## Reliable detection of all major HCV genotypes

**Diagnostic sensitivity:** 100% (95% confidence interval: 99.46-100%) testing 678 specimens from preselected individuals diagnosed with acute (n = 20) or chronic HCV infection (n = 40) as well as positive HCV serology (294 of whom encompassing genotypes 1, 2, 3, 4, 4 non-a, 5, 6).



# Confidence in Your results

## Exceptional specificity to reduce retesting

Population	Number of cases	Initially reactive samples, No.	Repeat reactive samples, No.	Diagnostic specificity, %	Diagnostic specificity, 95% CI
Blood donors	5274	17	16	99.70 (5258/5274)	99.51 - 99.83
Hospitalised patients	395	4	2	99.49 (393/395)	98.18 - 99.94
Dialysis patients	181	3	1	99.45 (180/181)	96.96 - 99.99
Pregnant women	100	1	1*	100.0 (99/99)	96.34 - 100.0
High-risk subjects	134	2	0	100.0 (134/134)	97.29 - 100.0

\* Specimen graded indeterminate by confirmatory test

## LIAISON® XL murex HCV Ab assay is flexible and easy to use

- Full automation makes your daily routine convenient and easy.
- Quick testing for better patient management.

<b>Standard Calibrator</b>	1 Calibrator included in the cartridge
<b>Controls</b>	Negative, Positive, ready to use (4 weeks stability)
<b>Interpretation of Results</b>	Specimens with signal-to-cut-off ratios above or equal to 1 are considered Reactive for HCV antibodies
<b>Minimum Sample Volume</b>	Routine = 25 µL Specimen plus 150 µL dead volume
<b>Sample Type</b>	Human serum or plasma (including serum collected in serum separator tubes). Anticoagulants: sodium citrate, potassium EDTA, lithium and sodium heparin, potassium oxalate, ACD, CPDA
<b>Reagent Stability</b>	Assay reagent (open on board stable 4 weeks)
<b>Reagent Preparation</b>	NS3 reagent (open on board stable 4 weeks)
<b>Precision (S/CO ≥ 1)</b>	Repeatability CV% < 10% - Interlot Reproducibility CV% < 13%

# LIAISON® XL **murex** HCV Ab

Improving performance and ease of use, targeting the best quality and safety in result reporting with LIAISON® XL system



- Quality in results reporting
- Consistent throughput up to 180 tests/h
- High reagent capacity & complete traceability
- High walk away time
- Service remote access

## Ordering Information

Product Name	Description	Code
LIAISON® XL murex HCV Ab*	100 tests	310240
LIAISON® XL murex Control HCV Ab (neg & pos)*	2 x 1.0 mL each	310241
LIAISON® XL	Platform	I0050
LIAISON® XL Cuvettes	7200/box	X0016
LIAISON® XL Disposable Tips	6912/box	X0015
LIAISON® XL Starter Kit	3000 test	319200
LIAISON® XL Wash/System Liquid	6 vials/box	319100
LIAISON® XL Waste Bags	50 bags/box	X0025

Product availability subject to required regulatory approval

### References

1. **F. Fabrizi et al** Novel assay using total hepatitis C Virus (HCV) core antigen quantification for diagnosis of HCV infection in dialysis patients. *J. Clinical Microbiology*, vol 43, n. 1, p 414-420, 2005.
2. **A Schnuriger et al** Early detection of Hepatitis C Virus (HCV) infection by use of a new combined antigen-antibody detection assay: potential use for high-risk individuals. *J. Clinical Microbiology*, vol. 44, n. 4, 1561-1563, 2006.
3. **S Laperche et al** Simultaneous detection of hepatitis C virus (HCV) core antigen and anti-HCV antibodies improves the early detection of HCV infection. *J. Clinical Microbiology*, vol. 43, n. 8, 3877-3883, 2005.
4. **JM Pawlotsky** Use and interpretation of virological tests for hepatitis C. *Hepatology*, vol. 36, n. 5, suppl. 1, 2002.

\*Available only for certain destinations

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