Hepatitis and Retrovirus

LIAISON® XL murex HCV Ab
Accurate diagnosis of the early stage of HCV infection

DiaSorin
The Diagnostic Specialist
FOR OUTSIDE THE US AND CANADA ONLY
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

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.
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**

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

* 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.

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**Standard Calibrator**
- 1 Calibrator included in the cartridge

**Controls**
- Negative, Positive, ready to use (4 weeks stability)

**Interpretation of Results**
- Specimens with signal-to-cut-off ratios above or equal to 1 are considered Reactive for HCV antibodies

**Minimum Sample Volume**
- Routine = 25 μL Specimen plus 150 μL dead volume

**Sample Type**
- Human serum or plasma (including serum collected in serum separator tubes). Anticoagulants: sodium citrate, potassium EDTA, lithium and sodium heparin, potassium oxalate, ACD, CPDA

**Reagent Stability**
- Assay reagent (open on board stable 4 weeks)

**Reagent Preparation**
- NS3 reagent (open on board stable 4 weeks)

**Precision (S/CO ≥ 1)**
- Repeatability CV% < 10% - Interlot Reproducibility CV% < 13%
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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Description</th>
<th>Code</th>
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<tbody>
<tr>
<td>LIAISON® XL murex HCV Ab *</td>
<td>100 tests</td>
<td>310240</td>
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<tr>
<td>LIAISON® XL murex Control HCV Ab (neg &amp; pos) *</td>
<td>2 x 1.0 mL each</td>
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<td>Platform</td>
<td>I0050</td>
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Product availability subject to required regulatory approval

*Available only for certain destinations

References