Hepatitis and Retrovirus

LIAISON® XL murex HIV Ab/Ag HT
A high throughput solution for HIV screening and diagnosis

FOR OUTSIDE THE US AND CANADA ONLY
Fast and high sensitive assay for an improved detection of HIV infection

Clinical background

Human immunodeficiency virus (HIV) is the aetiological agent of acquired immunodeficiency syndrome (AIDS). It is estimated that 35 million people are currently infected with HIV worldwide, with 2.1 million of new infected and 1.5 million of deaths every year. Due to the markers appearance during the course of HIV infection, the combined detection of antigen and antibodies against HIV is currently the most effective serological way to identify patients that have been recently infected.

HIV Screening and diagnosis

A high level of p24 Ag sensitivity is of utmost importance for an early detection. LIAISON® XL murex HIV Ab/Ag HT assay has showed an analytical sensitivity of 0.59 IU/mL (WHO First International Reference Reagent for HIV-1 p24 antigen, NIBSC code: 90/636), and 11.12 pg/mL (Afssaps standard), resulting in an excellent seroconversion sensitivity.

Combining an excellent specificity, and a high throughput, LIAISON® XL murex HIV Ab/Ag HT assay is a suitable aid in the diagnosis of HIV-1/HIV-2 infection and as a screening test for donated blood and plasma.

Diagnostic sensitivity

<table>
<thead>
<tr>
<th>Population</th>
<th>N. of cases</th>
<th>Diagnostic sensitivity, %</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-HIV-1-positive</td>
<td>856</td>
<td>100.0</td>
<td>99.57-100.0</td>
</tr>
<tr>
<td>Anti-HIV-O-positive</td>
<td>19</td>
<td>100.0</td>
<td>82.35-100.0</td>
</tr>
<tr>
<td>Anti-HIV-2-positive</td>
<td>302</td>
<td>100.0</td>
<td>98.79-100.0</td>
</tr>
<tr>
<td>Total</td>
<td>1,177</td>
<td>100.0</td>
<td>99.69-100.0</td>
</tr>
<tr>
<td>HIV p24-positive</td>
<td>146</td>
<td>100.0</td>
<td>97.51-100.0</td>
</tr>
</tbody>
</table>

Diagnostic specificity

<table>
<thead>
<tr>
<th>Population</th>
<th>N. of cases</th>
<th>Diagnostic specificity, %</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood donors</td>
<td>5,910</td>
<td>99.90</td>
<td>99.78-99.96</td>
</tr>
<tr>
<td>Hospitalized/diagnostic patients</td>
<td>2,094</td>
<td>99.81</td>
<td>99.51-99.95</td>
</tr>
</tbody>
</table>

Flexibility enables quick and reliable results

- Throughput: 171 test/h
- Time to 1st result: 32 minutes
- All reagents ready to use
- Sample volume: 200μL (plus 150μL dead volume)
- Sample: Serum or plasma
- One-point calibration, stable for 4 weeks
- Calibrator included in the reagent cartridge

Main features

- Number of tests: 200
- Platform: LIAISON® XL
- Instrument: fully automated
- Method: CLIA
- Assay format: Sandwich, qualitative
- Grayzone: None

Ordering information

LIAISON® XL murex HIV Ab/Ag HT (code 310290)
LIAISON® XL murex Control HIV Ab/Ag HT (code 310291)