Hepatitis and Retrovirus

LIAISON® XL murex Anti-HDV

Total automation for an accurate, easy and fast HDV diagnosis
Hepatitis and Retrovirus

Fast and fully automated assay for an improved detection of HDV infections

Clinical background
Hepatitis Delta is the most aggressive form of viral hepatitis and it is caused by HDV, the smallest human RNA virus. HDV occurs only as a co-infection in individuals harboring the Hepatitis B Virus (HBV) where an estimated 257 million people are infected with HBV worldwide. HDV leads to more severe liver disease than HBV alone and is associated with accelerated liver fibrosis, liver cancer, and liver failure. It is a disease with a significant impact on global health, which may affect up to approximately 15-20 million people worldwide.

The prevalence of HDV varies among different parts of the world. Globally, it ranges from 7% to 42%. The highest prevalence is seen in the Mediterranean basin, the Middle East, central and northern Asia, western and central Africa, the Amazonian basin, the Pacific islands and Vietnam. An HDV prevalence as high as 60% has being reported in HBV-infected patients in Mongolia and Pakistan. Due to the absence of an effective therapy, testing for hepatitis delta infection has been limited historically, but the increasing incidence and prevalence combined with the aggressiveness of this form of hepatitis, pose the need for increased HDV testing among chronic HBV patients.

HDV diagnosis
The parenteral route is the primary and most efficient for HDV transmission. Blood is potentially infectious during all phases of active hepatitis D infection. Peak infectivity probably occurs just before the onset of acute disease. Detection of total anti-HD antibodies is the first step in the diagnosis of HDV infection. Anti-HDV should be determined in all HBsAg carriers with liver disease. Anti-HD antibodies can be detected in high titres in HBsAg chronic carriers (superinfection) and, at lower titres, in patients with acute type B hepatitis (co-infection). Active HDV infection is diagnosed by the finding of HDV RNA.

The LIAISON® XL murex Anti-HDV assay uses chemiluminescence immunoassay (CLIA) technology for the qualitative detection of total antibodies to hepatitis D virus in human serum and plasma samples. The assay results, in conjunction with other laboratory results and clinical information, are intended to be used as an aid in the diagnosis of HDV infection and as a screening test for organ and tissue donors.

Flexibility enables quick and reliable results
- Diagnostic sensitivity: 100% (95% C.I.: 97.90 – 100%)
- Diagnostic specificity: 99.35% (95% C.I.: 98.89 – 99.66%)
- Throughput: up to 171 tests/h (LIAISON® XL); up to 90 tests/h (LIAISON®)
- Time to 1st result: 32 minutes
- Low sample volume: 20 µL plus 150 µL dead volume
- High reagent stability on board: 10 weeks
- Calibration stable for 6 weeks
- Calibrators included in the reagent cartridge
- All reagents ready to use

Main Features
- Number of tests: 100
- Platform: LIAISON® and LIAISON® XL
- Serum, plasma and cadaveric specimens
- Solid phase: recombinant HDV antigen
- Conjugate: mouse monoclonal IgG to human IgG and IgM
- Label: isoluminol derivative
- Assay format: indirect, qualitative
- No grayzone

Management flow of HDV infection*

<table>
<thead>
<tr>
<th>Management flow of HDV infection*</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg</td>
</tr>
<tr>
<td>(-) HCV RNA (+)</td>
</tr>
<tr>
<td>Treat underlying HBV infection</td>
</tr>
</tbody>
</table>

*adapted from Hughes et al.

References:

Ordering information
LIAISON® XL murex Anti-HDV (code 311260)  LIAISON® XL murex Control Anti-HDV (code 311261)

Product availability subject to required regulatory approval