Is your laboratory prepared for Lyme disease?

Vidas
Lyme IgG II™
Lyme IgM II™

- Rapid results in just 27 minutes
- Cost-effective, streamlined workflow
- High sensitivity and specificity
High Specificity and Sensitivity

The VIDAS® Lyme IgG II™ assay contains a combination of 3 recombinant chimeric *Borrelia burgdorferi* sensu lato proteins (VlSE, DbpA, and OspC).

- Outer surface proteins (OspC, DbpA, VlSE) play a major role in the immune response of the infected host. Additionally, all three antigens used in these assays have been shown to be immunogenic during human infection.\(^5\)
  - OspC (Outer surface protein C) is essential to establish *Borrelia* infection, essentially produced \textit{in vivo}.
  - DbpA (Decorin-binding protein A) outer surface protein produced by *Borrelia*, essentially \textit{in vivo}.
  - VlSE (Variable major protein-like sequence), expressed \textit{in vivo} presents a highly immunogenic conserved region, used for serodiagnosis.

"When using the LYM/LYG EIAs as a first-tier test followed by the C6 EIA as a second-tier test, it should be noted that the LYG EIA uses VlSE as one of three test antigens. VlSE is an immunogenic variable surface protein of *B. burgdorferi* that contains two invariable domains at each terminus, and a central domain that is composed of six variable and six invariable regions (IRs).\(^2,5\) C6 is the sixth invariable region (IR6) of the central domain of VlSE."\(^4\)

Less rework and clinically unnecessary confirmatory tests.

"Sensitivities of 68 to 69% and 76 to 77% and specificities of 97% and 98 to 99% resulted when the two EIA strategies were followed by Western immunoblotting and when used in a MTTT [Modified Two-Tier Testing], respectively. The MTTT approach resulted in significantly higher sensitivities as compared to STTT."\(^5\)

"Although immunoblot assays are reduced in the second-tier test, two EIAs need to be performed in the first tier and the total number of tests (first and second tier) required is dependent on the rate of positive first-tier results."\(^5\)

![Figure 1: CDC Confirmed Immunoblot Reduction](image)

Adapted from Molins\(^5\)
Advantages

**Differentiated serological profile**

- Facilitates classification of Lyme borreliosis: early or late/chronic, active or immune
- Helps ensure patients receive rapid, optimized treatment depending on their stage of infection
- Potential to deduce information on disease progression (based on IgM and/or IgG positivity)

**Better patient management^1^ and only patients with Lyme borreliosis are treated**

- Innovative recombinant chimeric proteins (VlsE, DbpA, OspC) allowing detection of all main pathogenic *Borrelia* strains (sensu stricto, afzelii, garinii). The design of the chimeric protein constructs includes C6 (the VlsE invariant region IR6), which allows the VIDAS® Lyme IgG II™ assay to provide high sensitivity and specificity and limit cross reactivity
- Low level of cross-reaction (syphilis, other infectious diseases)

“The LYT EIA had higher cross-reactivity when other diseases were tested (73% specificity) than the LYM/LYG EIAs (91% and 82% specificity when duration of illness was considered and not considered, respectively).”^5^

**Easy result interpretation**

- No equivocal zone for VIDAS® Lyme IgG II™ results
- Avoid unnecessary patient anxiety and additional testing

**Streamlined workflow, rapid results**

- Results in 27 minutes
- Calibration only once every 28 days
- Ease-of-use
- Single-dose tests

**Cost effective^5^6**

- Decreased number of total immunoblots that are needed for second-tier testing
- Reduction in costs associated with immunoblots
- Reduction in the level of specialized training that is required to properly perform an EIA as compared to immunoblotting
Lyme IgG II™
Lyme IgM II™

Differential diagnosis
in just 27 minutes

Serological Profile
• Facilitates classification of Lyme borreliosis: early or late/chronic, active or immune
• Helps ensure patients receive rapid, optimized treatment depending on their stage of infection

High specificity and sensitivity
• Innovative recombinant chimeric proteins* (VlsE, DbpA, OspC) allowing detection of all main pathogenic Borrelia strains (sensu stricto, afzelii, garinii)

• Less rework and unnecessary confirmatory tests
• Low level of cross-reaction (syphilis, other infectious diseases)
• Better patient management

Only patients with Lyme borreliosis are treated

Technical Specifications

<table>
<thead>
<tr>
<th>VIDAS® Lyme IgG II™</th>
<th>VIDAS® Lyme IgM II™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code</td>
<td>LYG</td>
</tr>
<tr>
<td>Reference</td>
<td>417401</td>
</tr>
<tr>
<td>Tests/kit</td>
<td>60 tests</td>
</tr>
<tr>
<td>Sample type</td>
<td>Plasma, serum</td>
</tr>
<tr>
<td>Sample volume</td>
<td>100 µl</td>
</tr>
<tr>
<td>Calibration</td>
<td>1 level every 28 days</td>
</tr>
<tr>
<td>Time to result</td>
<td>27 minutes</td>
</tr>
<tr>
<td>Results</td>
<td>Qualitative; no equivocal range</td>
</tr>
</tbody>
</table>

* Patent pending no. PCT/FR2010/051787 and no. PCT/FR2010/051780

CPT Code: 86618
CPT Code Modifier: –59

Order online at bioMerieuxDIRECT.com

References
1. VIDAS® Lyme IgG II™ and VIDAS® Lyme IgM II™ package inserts