FOR OUTSIDE THE US AND CANADA ONLY

LIAISON® LymeDetect®

The new paradigm in EARLY Lyme borreliosis detection

DiaSorin
The Diagnostic Specialist
LIAISON® LymeDetect®

LIAISON® LymeDetect® is an innovative approach to EARLY Lyme disease diagnostics that combines assays measuring B cell response, LIAISON® IgG and IgM CLIA assays, and T cell response with the patented QuantiFERON® IGRA technology.

This new diagnostic solution has demonstrated a significant improvement in sensitivity vs standard two-tiered testing (sTTT) in the first 21 days of the infection, from 48.5% (sTTT) to the 73.5% of LIAISON® LymeDetect®.

The fully automated and traceable workflow allows easy integration in the current lab routine and virtually eliminates the cumbersome hands-on and subjective reading of the current standard of care.

Lyme borreliosis is among the world’s fastest growing infectious diseases and one of the most difficult to diagnose. If left untreated, the multi-organ tickborne infection can cause neuropathy, meningitis, cardiac conduction abnormalities, and arthritis.

- Clinical diagnosis is only easy if accompanied by the typical bull's eye rash
- 30% of infected patients manifest nonspecific symptoms
- Many don't realize they've been bitten by a tick
- Until now, EARLY detection has been difficult and not reliable in all stages of the infection

Standard two-tiered testing (sTTT) has a low sensitivity in the EARLY stages of Lyme disease. Furthermore, obtaining final results can take days, if not weeks. The current standard is also limited by its technical complexity, cumbersome hands-on process (1) and the controversial specificity of immunoblotting. (2,3)

EARLY diagnosis of Lyme disease can identify and treat patients before severe illness develops.

Although the clinical disease can manifest just days following an infectious tick bite, (4,5) serologic sTTT is unable to respond to EARLY detection needs.

LIAISON® LymeDetect® combines proven LIAISON® Borrelia IgG and IgM CLIA assays with patented QuantiFERON® IGRA technology improving sensitivity in EARLY diagnosis from 48.5% to 73.5% compared to sTTT. (6)
**A powerful new approach**

LIAISON® LymeDetect® tests both B cell humoral immunity and T cell mediated immunity to effectively diagnose Lyme disease \(^7\) within weeks of contact with an infected tick. Unlike manual processes, which introduce the likelihood of simple human error, LIAISON® LymeDetect® is a closed-loop system that ensures clear, reliable diagnostics for optimized workflows and better results.

**As innovative as it is intuitive**

After loading the three reagent integrals on the LIAISON® XL or LIAISON® XS analyzer to automatically perform the CLIA assays, results are combined in a single qualitative assay. Giving you a clear diagnosis in as little as 24 hours.

**The adaptive immunity advantage**

![Diagram of adaptive immunity]

The leading DiaSorin *B. burgdorferi* IgG and IgM serology biomarkers
- Help detect patient immunization

The leading QuantiFERON® IGRA technology
- Marker of cell-mediated immunity (CMI)
- Secreted, stable, measurable
- Generally absent from normal circulation

Due to IgG and IgM assay limitations, LIAISON® LymeDetect® seeks additional information from the T cells.
- T cell activation may provide more accurate information on the presence of active infection compared to antibody responses \(^7\)
- Strong Interferon-gamma (IFN–gamma) responses to *B. burgdorferi* antigens after the initial infection make interferon gamma release assays (IGRAs) capable of detecting the infection earlier than antibody tests during the serologic window period.\(^7\)
- Combining information from standard serological testing and IGRA leads to higher sensitivity for early Lyme Disease detection (83% combined IGRA serology vs 59% serology only) \(^8\)
Most international guidelines recommend diagnosing Lyme disease clinically and in conjunction with laboratory serology tests.\(^{(1)}\)

Yet because clinical symptoms take around 3 weeks to manifest, serology testing is done long after *B. burgdorferi* bacteria has infected the body.

Furthermore, even once the bacteria has begun to spread to nearby tissue, sTTT is prone to false negative results if a patient's antibody levels are low.

LIAISON® LymeDetect® is the ideal solution for EARLY Lyme disease detection with a 50% higher diagnostic sensitivity compared with sTTT during the first 3-4 weeks of infection.\(^{(7)}\)

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**sTTT diagnostic flowchart**

Use clinical presentation and laboratory testing to guide diagnosis. If there is a high clinical suspicion of Lyme disease:
- consider starting treatment while waiting for test results
- do not rule out Lyme disease even if results are negative

**Diagnose Lyme disease:**
- offer antibiotics

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**One clear result in one single step**

LIAISON® LymeDetect® ensures reliable EARLY Lyme borreliosis detection while offering the added flexibility to personalize the workflow to best suit your routine.

Run the two CLIA assays in the same run, or run them in two separate runs as soon as each sample is ready – the choice is yours.

Either way, results are combined into a single qualitative assay to deliver fast, complete diagnostic performance without compromise.
Clinical performance of LIAISON® LymeDetect® has been established with 309 specimens prospectively collected at five European clinical sites from Lyme Borreliosis patients with and without signs of Erythema Migrans and from healthy subjects.

<table>
<thead>
<tr>
<th></th>
<th>Lyme patients</th>
<th>Healthy Subjects</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>123</td>
<td>186</td>
<td>309</td>
</tr>
</tbody>
</table>

123 Lyme patients were recruited in endemic areas and tested with both the LIAISON® LymeDetect® assay and the standard two-tiered test (sTTT).

105 out of 123 patients had evidence of Erythema Migrans, while 18 did not show signs of Erythema Migrans, for a rate of 14.6% (18/123).

After testing with LIAISON® LymeDetect® assay, Lyme patients were classified into two categories: within 21 days from onset of evidence (i.e. appearance of the Erythema Migrans or from the tick bite); and more than 21 days.

<table>
<thead>
<tr>
<th></th>
<th>LymeDetect® Algorithm</th>
<th>sTTT Algorithm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elapsed time*</td>
<td>Diagnostic Sensitivity</td>
<td>Wilson 95% CI</td>
</tr>
<tr>
<td>≤ 21 days</td>
<td>73.53% (50/68)</td>
<td>61.99% - 82.55%</td>
</tr>
<tr>
<td>&gt; 21 days</td>
<td>81.82% (45/55)</td>
<td>69.67% - 89.81%</td>
</tr>
</tbody>
</table>

Diagnostic specificity was evaluated with the LIAISON® LymeDetect® assay based on 186 healthy subjects

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<th>sTTT Algorithm</th>
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<tr>
<td>Healthy subjects</td>
<td>Diagnostic Sensitivity</td>
<td>Wilson 95% CI</td>
</tr>
<tr>
<td></td>
<td>100% (186/186)</td>
<td>97.98% - 100%</td>
</tr>
</tbody>
</table>

*LIAISON®, LymeDetect®, QuantiFERON®, and Blood Collection Tubes are trademarks and/or registered trademarks of bioMérieux Inc.

LIAISON® LymeDetect® combines the market leading LIAISON® Borrelia IgG and IgM CLIA assays with the patented QuantiFERON® IGRA technology, providing the highest quality and fully automated EARLY Lyme borreliosis detection tool in the market.

LIAISON® LymeDetect® IgG and LIAISON® LymeDetect® IgM qualitatively detect B. burgdorferi sensu lato (including strains B. burgdorferi sensu stricto, B. garinii, B. afzelii) IgG and IgM specific antibodies in human serum and plasma specimens

LIAISON® QuantiFERON® LymeDetect® measures the T cell mediated immune response in heparinized whole blood to a peptide antigens cocktail associated with Borrelia burgdorferi sensu lato infection, contained in the QuantiFERON® LymeDetect® Blood Collection Tubes

LIAISON® QuantiFERON® LymeDetect® Blood Collection Tubes, three lithium-heparin tube types for the collection of whole blood, stimulate T cells sensitized to B. burgdorferi secrete IFN-gamma which is measured in the QuantiFERON® LymeDetect® read-out components and combined in a qualitative result

All three individual results are then combined to deliver a single, comprehensive qualitative diagnosis.
Sample management

Patient samples are collected in serum or plasma collection tubes for serology testing, and in LIAISON® QuantiFERON® LymeDetect® Blood Collection Tubes for LIAISON® QuantiFERON® LymeDetect® incubation and IFN-gamma detection.

Nil

Negative patient control

Adjusts for background noise or non-specific IFN-gamma in blood samples
Easy, efficient and highly reliable

With concrete performance in the EARLY detection of Lyme disease, LIAISON® LymeDetect® delivers the diagnostic innovation you can rely on to optimize your workflow while differentiating your lab.

**Lyme**
Contains highly specific *B. burgdorferi* antigens stimulating immunized T cells to produce IFN-gamma

**Mitogen**
Positive patient control
**LIAISON® LymeDetect®**

Ordering Information & Specifications Reagent

<table>
<thead>
<tr>
<th>LIAISON® LymeDetect®</th>
<th>311030</th>
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<tbody>
<tr>
<td>KIT FORMAT</td>
<td>65 patients/kit</td>
</tr>
<tr>
<td></td>
<td>3 integrals (LymeDetect® IgG, LymeDetect® IgM, QuantiFERON® LymeDetect®)</td>
</tr>
<tr>
<td>TIME TO FIRST RESULT</td>
<td>45 min</td>
</tr>
<tr>
<td>OPEN/ON BOARD KIT STABILITY</td>
<td>28 days</td>
</tr>
<tr>
<td>CALIBRATION STABILITY</td>
<td>28 days</td>
</tr>
<tr>
<td>No Biotin potential inference observed</td>
<td>Up to 3500 ng/mL</td>
</tr>
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**Controls**

<table>
<thead>
<tr>
<th>LIAISON® Contol LymeDetect®</th>
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</thead>
<tbody>
<tr>
<td>KIT FORMAT</td>
<td>2 x 5 Control vials</td>
</tr>
<tr>
<td></td>
<td>2 x B. burgdorferi IgG/IgM Negative control</td>
</tr>
<tr>
<td></td>
<td>2 x B. burgdorferi IgG positive control</td>
</tr>
<tr>
<td></td>
<td>2 x B. burgdorferi IgM positive control</td>
</tr>
<tr>
<td></td>
<td>2 x 2 levels QuantiFERON® LymeDetect® controls (lyophilised)</td>
</tr>
<tr>
<td>RECONSTITUTED/OPEN STABILITY at 2°-8°C</td>
<td>28 days</td>
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**Blood collection tubes**

<table>
<thead>
<tr>
<th>LIAISON® QuantiFERON® LymeDetect® Blood Collection Tubes</th>
<th>311035</th>
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</thead>
<tbody>
<tr>
<td>KIT FORMAT</td>
<td>100 patient tube sets</td>
</tr>
<tr>
<td></td>
<td>2 x 50 LIAISON® QuantiFERON® LymeDetect® Nil</td>
</tr>
<tr>
<td></td>
<td>2 x 50 LIAISON® QuantiFERON® LymeDetect® Mitogen</td>
</tr>
<tr>
<td></td>
<td>2 x 50 LIAISON® QuantiFERON® LymeDetect® Lyme</td>
</tr>
</tbody>
</table>

References:
6. LIAISON® LymeDetect® IFU P/N 311030

Product availability subject to required regulatory approval

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