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LIAISON® LymeDetect®

The new paradigm in EARLY Lyme borreliosis detection

INFECTIOUS DISEASES

FOR OUTSIDE THE US AND CANADA ONLY

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The Diagnostic Specialist

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The new paradigm in EARLY Lyme borreliosis detection

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 disease is a growing concern

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

Limitations of the current standard of care

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]

Faster detection means fewer health issues

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

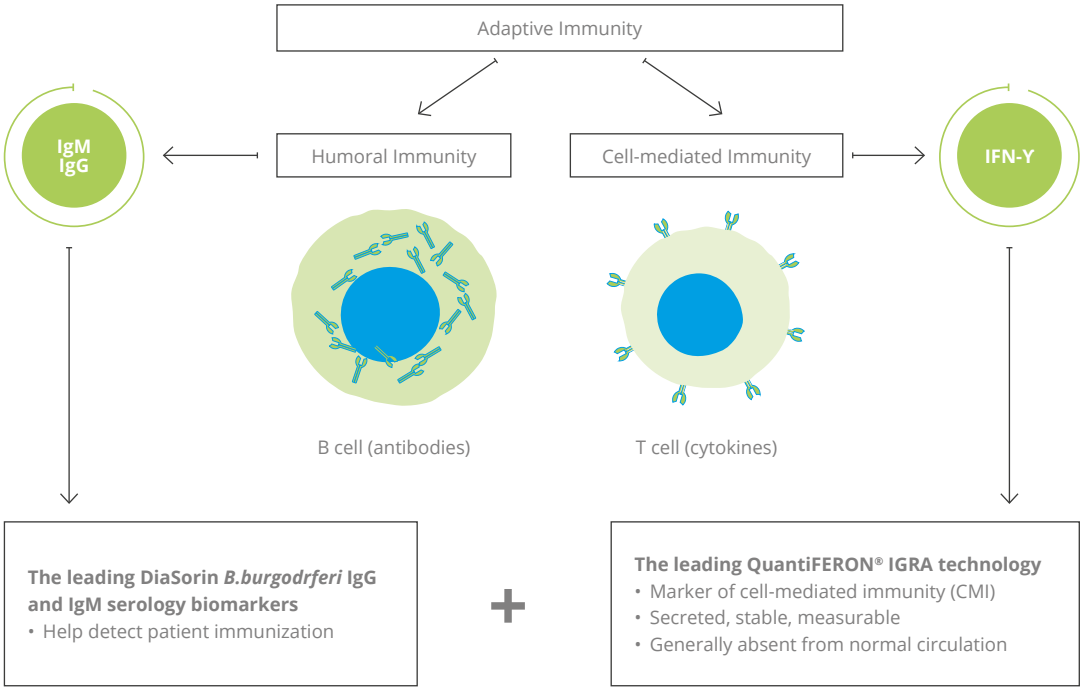
LIAISON® LymeDetect® tests both B cell humoral immunity and T cell mediated immunity to effectively diagnose Lyme disease [7] within weeks of contact with an infected tick.

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



The diagnostic value of T cells

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]

Key considerations

Most international guidelines recommend diagnosing Lyme disease clinically and in conjunction with laboratory serology tests. [1]

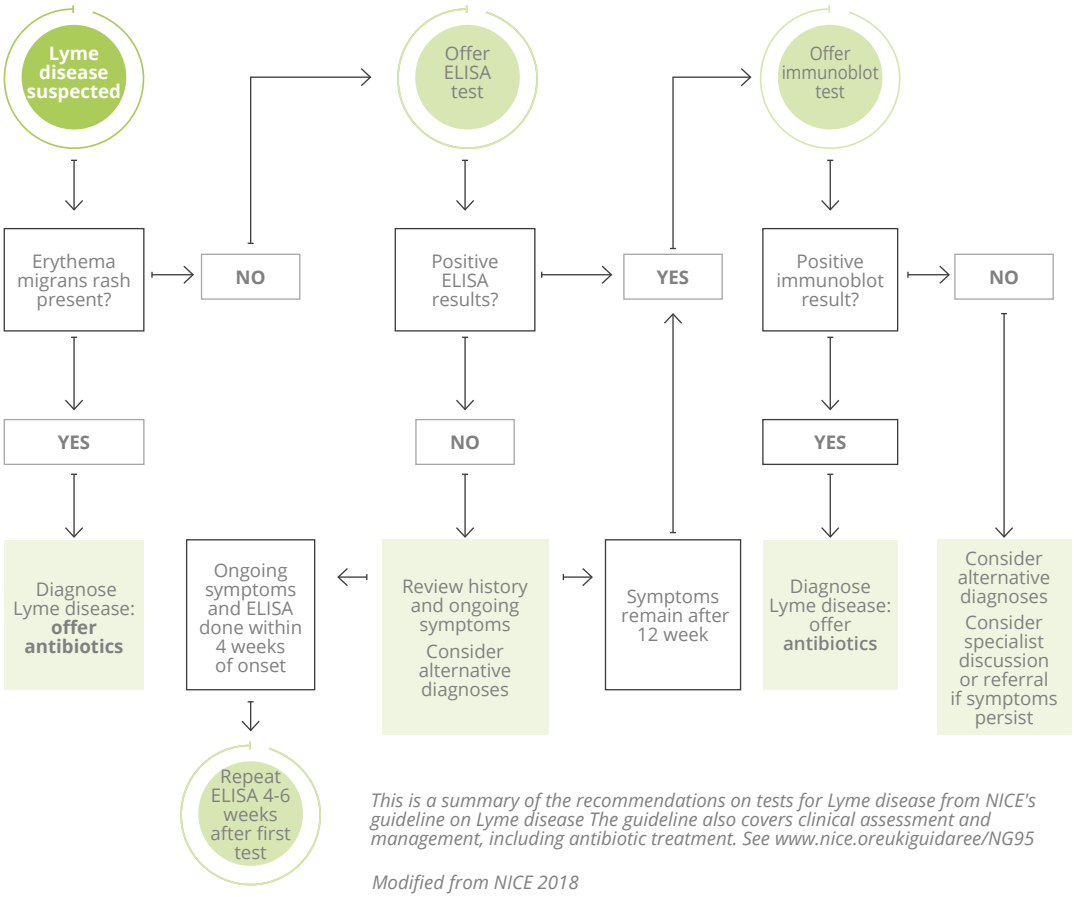
Yet because clinical symptoms take around 3 weeks to manifest, serology testing is done long after *B. burgdorferi* bacteria has infected the body.

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]

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



This is a summary of the recommendations on tests for Lyme disease from NICE's guideline on Lyme disease The guideline also covers clinical assessment and management, including antibiotic treatment. See www.nice.oreukiguidaree/NG95

Modified from NICE 2018

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

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.

Lyme patients	Healthy Subjects	Total
123	186	309

Over 50% higher diagnostic sensitivity in EARLY stages

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.

	LymeDetect® Algorithm		sTTT Algorithm	
Elapsed time*	Diagnostic Sensitivity	Wilson 95% CI	Diagnostic Sensitivity	Wilson 95% CI
≤ 21 days	73.53% (50/68)	61.99% - 82.55%	48.53% (33/68)	37.05% - 60.17%
> 21 days	81.82% (45/55)	69.67% - 89.81%	67.27% (37/55)	54.10% - 78.19%

Optimal diagnostic specificity

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

	LymeDetect® Algorithm		sTTT Algorithm
	Diagnostic Specificity	Wilson 95% CI	Diagnostic Specificity*
Healthy subjects	100% (186/186)	97.98% - 100%	95%

**data inferred by the literature [10]*

Product description

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.

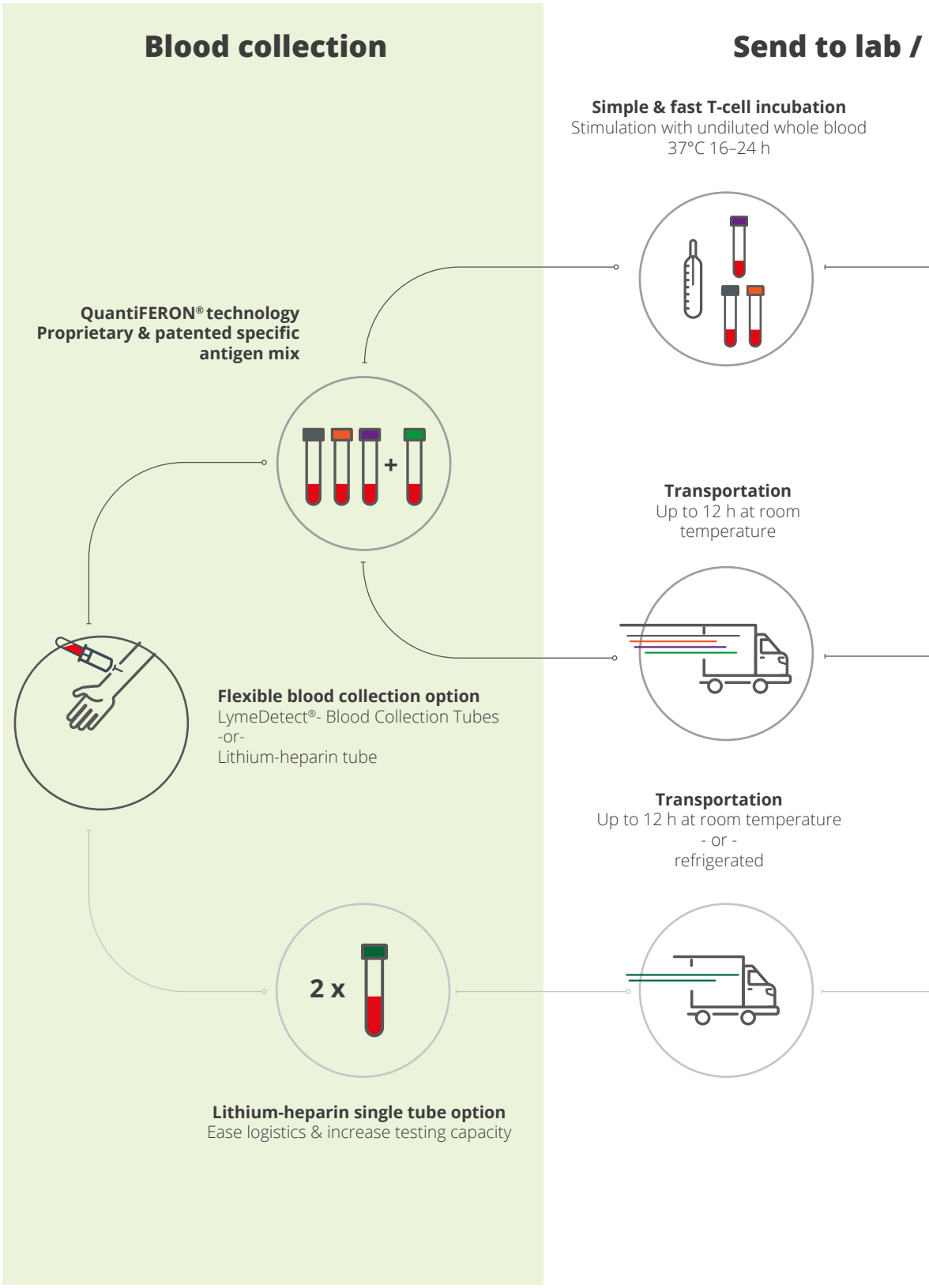
LIAISON® LymeDetect® IgG and LIAISON® LymeDetect® IgM qualitatively detect *B. burgdorferi* sensu lato (including strains *B. burgdorferi sensu stricto, B. garinii, B. afzelii*) IgG and IgM specific antibodies in human serum and plasma specimens

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

Optimized workflow and efficiency



Nil Negative patient control

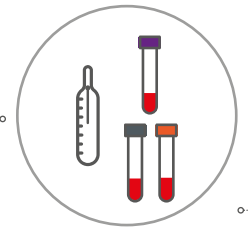
Adjusts for background noise or non-specific IFN-gamma in blood samples

Sample management

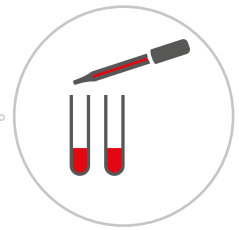
Patient samples are collected in serum or plasma collection tubes for serology testing, and in LIAISON® QuantiFERON® LymeDetect® Blood Collection Tubes for LIAISON® QuantiFERON® LymeDetect® incubation and IFN-gamma detection.

Stimulation

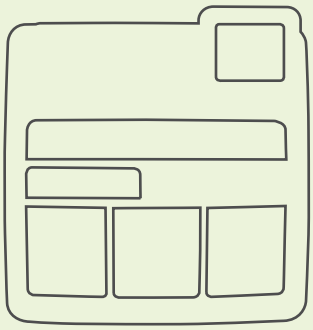
Transportation
Up to 3 days at 17–27°C

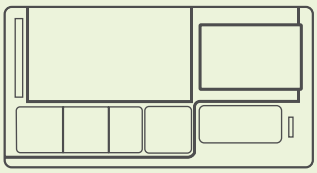


Transferring to LymeDetect® Blood Collection Tubes



Fully automated serology + IGRA testing



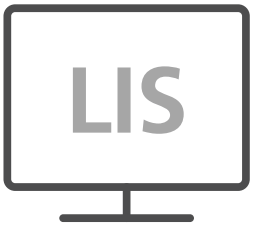


Easy integration
Random access mode
Continuous loading
Limited footprint

CLIA technology
LIAISON® serology and QuantiFERON® assays within a broad menu of >120 assays

Rapid & robust
46 min to 1st results
High throughput

Results & Interpretation



Bi-direction LIS connection
Fully traceable workflow

Automatic result interpetation

LIAISON® asyc

(optional)
Automatic result interpretation

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

Mitogen Positive patient control

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.

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Ordering Information & Specifications Reagent

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

Controls

LIAISON® Contol LymeDetect®	311031
KIT FORMAT	2 x 5 Control vials 2 x *B. burgdorferi* IgG/IgM Negative control 2 x *B. burgdorferi* IgG positive control 2 x *B. burgdorferi* IgM positive control 2 x 2 levels QuantiFERON® LymeDetect® controls (lyophilised)
RECONSTITUTED/OPEN STABILITY at 2°-8°C	28 days

Blood collection tubes

LIAISON® QuantiFERON® LymeDetect® Blood Collection Tubes	311035
KIT FORMAT	100 patient tube sets 2 x 50 LIAISON® QuantiFERON® LymeDetect® Nil 2 x 50 LIAISON® QuantiFERON® LymeDetect® Mitogen 2 x 50 LIAISON® QuantiFERON® LymeDetect® Lyme

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7. 7. Branda et al. 2021. Laboratory diagnosis of Lyme borreliosis. Clin Microbiol Rev 34:e00018-19
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Product availability subject to required regulatory approval

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