

## Borrelia burgdorferi IgG, IgM

### ■ Searching for diagnostic clarity: LIAISON® Borrelia serology line

The diagnosis of Lyme borreliosis is based on clinical manifestations and history of exposure to ticks in an endemic area. Clinical manifestation of Lyme borreliosis may be similar to that of other diseases, and serological detection of Borrelia antibodies represents a **fundamental aid to diagnosis** (Fig. 1).

Tests with high diagnostic accuracy are particularly important for differential diagnosis since additional factors complicate serological findings:

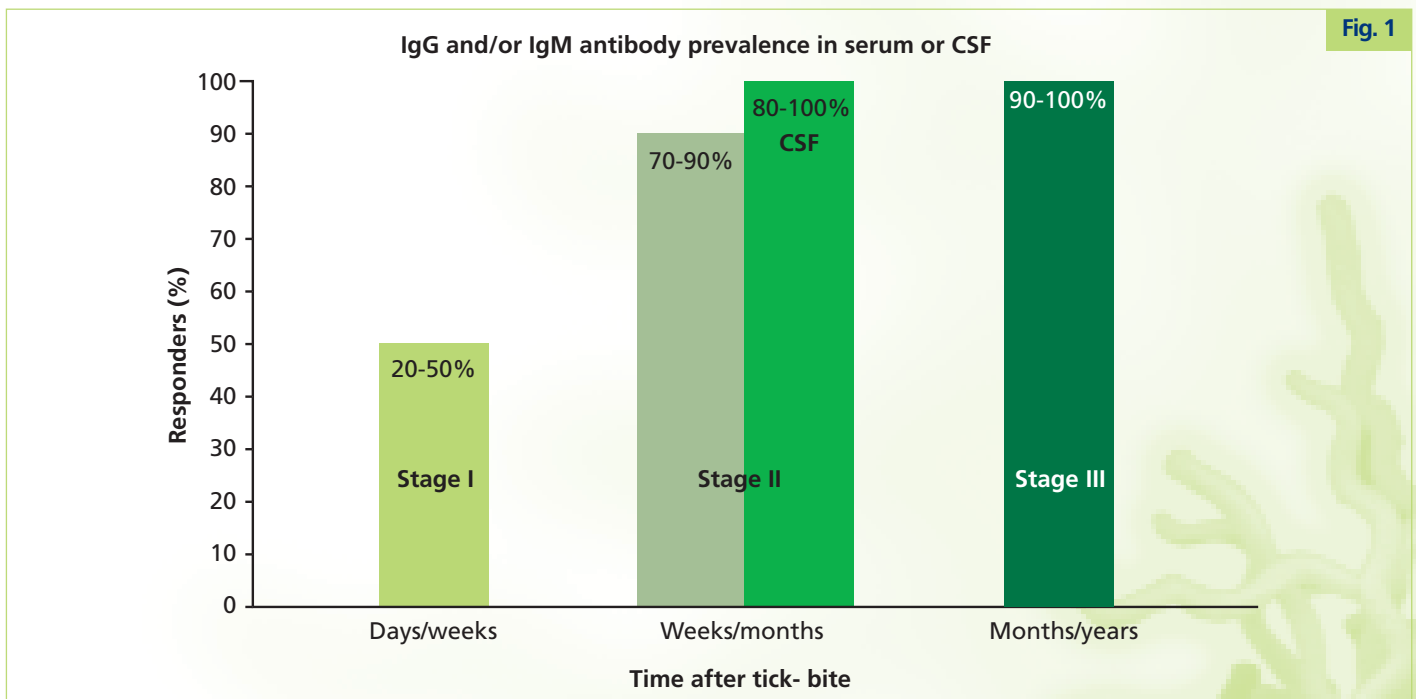
- early stage of infection may not show a measurable immune response
- IgM antibodies may persist for months
- cross-reaction with other spirochaete proteins, or other infectious diseases or autoimmune disorders may cause false positive antibody response

A substantial progress in solving diagnostic ambiguities, has been achieved with the LIAISON® Borrelia line.

### ■ Unique selection of raw materials

The LIAISON® Borrelia assays are based on **recombinant** proteins that allow reduction of cross-reactivity problems providing **higher specificity** in comparison with whole-cell lysate assays. The use of immunodominant Borrelia antigens, VlsE for IgG assay, OspC and VlsE for IgM assay, have **improved the diagnostic sensitivity** in all stages of Lyme infection.

- LIAISON® Borrelia IgG features the antigen **VlsE**, an outer surface lipoprotein playing a major role in the immune response to Lyme disease and leading to decisive increase of sensitivity in neuroborreliosis (NB). The VlsE antigen is poorly represented in whole-cell lysate obtained from in vitro cultured *B. burgdorferi*.
- LIAISON® Borrelia IgM Quant uses two recombinant antigens: **OspC**, an outer surface protein highly specific for IgM detection in the early phase of infection and **VlsE** protein. This antigen combination guarantees a higher diagnostic sensitivity, making this assay the most suitable diagnostic tool for laboratory diagnosis during the early stages of Lyme disease and especially in neuroborreliosis.



Clinical condition	Number of samples	IgG % positive	IgM % positive	IgG and/or IgM % positive
Erythema migrans	45	80.0	55.6	88.9
Neuroborreliosis	57	93.0	57.9	96.5
Arthritis	39	97.4	30.8	97.4

Table 1

**LIAISON® Borrelia IgM Quant and Borrelia IgG: serum and CSF quantitative detection**

Neuroborreliosis is a serious inflammatory disease of the peripheral and central nervous system.

The diagnosis of neuroborreliosis is a clinical decision which should be supported by laboratory data. The first step would be testing for specific antibodies in serum and investigation of the CSF. The detection of *B. burgdorferi* specific antibodies in CSF is suggestive of intrathecally-synthesized antibodies when evaluated in association with other laboratory findings.

LIAISON® Borrelia IgM Quant and LIAISON® Borrelia IgG are the first fully automated assays for **quantitative** measurement of specific IgM and IgG antibodies in serum and in CSF. LIAISON® Borrelia assays permit the test of serum and CSF in the same assay run, with the same reagent cartridge using two different specimen dilutions performed by the instrument.

**Assay format ensures reliable results**

The diagnostic sensitivity was determined in a clinical study performed at the German National Reference Center for Borreliae by testing 141 serum specimens from patients with clinically characterized Lyme borreliosis (Table 1).

The diagnostic specificity was determined by testing serum specimens from subjects living in an endemic area and without history of tick contact or Lyme disease:

**LIAISON® Borrelia IgM Quant (88 samples)**  
Diagnostic specificity 96.6% (95% CI: 90.4-99.3%)

**LIAISON® Borrelia IgG (100 samples)**  
Diagnostic specificity 98.0% (95% CI: 93.0-100%)

**Flexibility enables quick results**

- **Number of tests:** 100
- **High throughput**
  - Borrelia IgG: 90 results/hour
  - Borrelia IgM Quant: 45 results/hour
- **Time to first result**
  - Borrelia IgG, Borrelia IgM Quant: 35 min
- **Assays format: quantitative assays**
  - Borrelia IgG: 0-240 AU/mL
  - Borrelia IgM Quant: 0-190 AU/mL

• **Tiny sample volume**

<b>Borrelia IgG</b>	Serum	5 µL
	CSF	50 µL
<b>Borrelia IgM Quant</b>	Serum	10 µL
	CSF	50 µL

• **Specimen dilutions**

<b>Borrelia IgG</b>	Serum	1:50
	CSF	1:5
<b>Borrelia IgM Quant</b>	Serum	1:147
	CSF	1:2.6