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

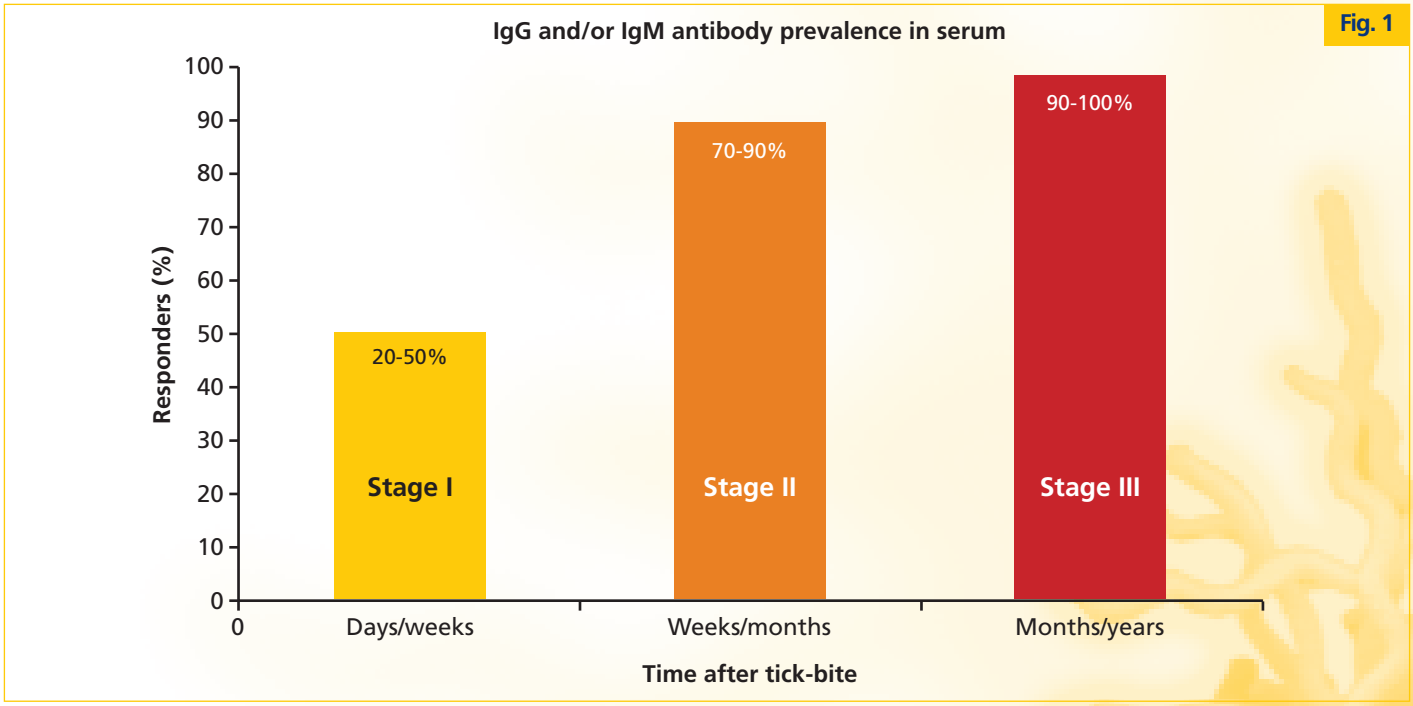
A substantial progress in solving diagnostic ambiguities, has been achieved with the LIAISON® Borrelia line.

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, has **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 II** uses two recombinant antigens: **OspC**, an outer surface protein highly specific for IgM detection in the early phase of infection, and the **VlsE** protein. This antigen combination guarantees an higher diagnostic sensitivity, making this assay a suitable diagnostic tool for laboratory diagnosis during the early stages of Lyme disease.

Fig. 1



LIAISON®

NEW!
IgM improved detection:
OspC + VlsE

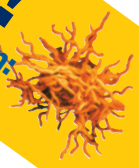


Table 1

Clinical condition	Number of samples	IgG % positive	IgM % positive	IgG and/or IgM % positive
Erythema migrans	45	80.0	46.7	88.9
Neuroborreliosis	57	93.0	43.9	96.5
Arthritis	39	97.4	25.6	97.4

Assay format ensures reliable results

All guidelines for microbiological diagnosis of Lyme borreliosis recommend a two-test approach using a sensitive assay, differentiating IgM and IgG, followed by a confirmatory assay.
LIAISON® Borrelia IgG and LIAISON® Borrelia IgM II are the first fully automated assays for measurement of specific IgM and IgG antibodies. The combined result, obtained with LIAISON® Borrelia IgM II and LIAISON® Borrelia IgG, represents an highly sensitive and specific screening tool for Lyme disease.

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 II (88 samples)
Diagnostic specificity 100% (95% CI: 95.9-100%)

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 II: 45 results/hour
- **Time to first result**
  - Borrelia IgG, Borrelia IgM II: 35 min
- **Assays format**
  - Borrelia IgG: quantitative assay (0-240 AU/mL)
  - Borrelia IgM II: qualitative assay (0-6 Index)
- **Tiny sample volume**

Borrelia IgG	Serum	5 µL
	CSF	50 µL
Borrelia IgM II	Serum	10 µL

- **Specimen dilutions**

Borrelia IgG	Serum	1:50
	CSF	1:5
Borrelia IgM II	Serum	1:147