Borrelia burgdorferi infection?

LIAISON® Borrelia IgG and IgM assays

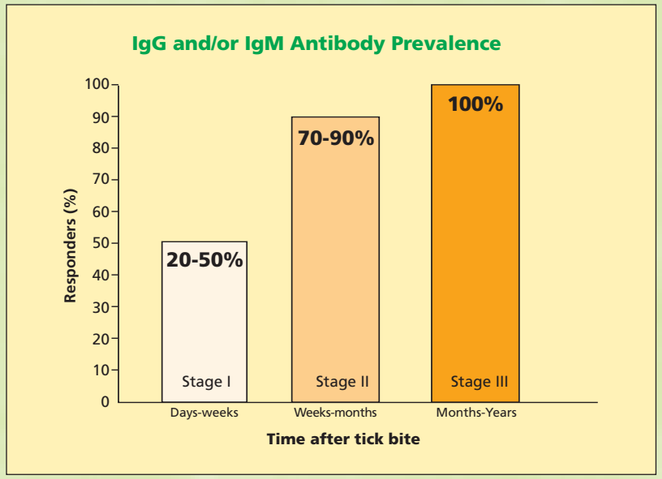
Confidence in Your Results

Searching for diagnostic clarity: DiaSorin 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 other diseases, and serological detection of Borrelia antibodies represents a **fundamental aid to diagnosis**.
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 to other spirochete 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.
The LIAISON® assays are based on immunodominant Borrelia antigens: Osp C and the recently identified VlsE.
These recombinant proteins allow a **superior diagnostic sensitivity and reduce cross-reactivity** problems, providing a **higher specificity** in comparison with whole-cell lysate assays.



A unique selection of raw materials

Use of recombinant proteins excludes cross-reactions with other spirochete proteins

* **VlsE: LIAISON® Borrelia IgG** features the antigen VlsE, an outer surface lipoprotein playing a major role in the immune response to Lyme disease. The VlsE antigen is poorly represented in whole-cell lysate obtained from in vitro cultured *B. burgdorferi*.
* **OspC: LIAISON® Borrelia IgM** features the antigen Osp C, an outer surface protein highly specific for IgM detection in the early phase of infection. The use of this immunodominant antigen for IgM response avoids the interference of rheumatoid factor antibodies as well as IgG and IgM competition for the binding sites.

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 154 serum specimens from patients with Lyme borreliosis. The IgG and IgM results should be judged in combination to achieve the best diagnostic sensitivity.

Clinical symptom categories	Number of samples	IgG % of positive	IgM % of positive	IgG and/or IgM % of positive
Erythema migrans	51	74.5	52.9	86.3
Neuroborreliosis	59	91.5	42.4	96.6
Arthritis	44	97.7	15.9	97.7

The diagnostic specificity was determined by testing 100 serum specimens from subjects living in an endemic area and without history of tick contact or Lyme disease:

LIAISON® Borrelia IgM diagnostic specificity of 99.0% (95% CI: 94.6-100%)
LIAISON® Borrelia IgG diagnostic specificity of 98.0% (95% CI: 93.0-100%)

Assay format allows excellent discrimination between negative and positive results

A prospective study was performed with 300 routine serum specimens, comparing the LIAISON® Borrelia assays and reference enzyme immunoassays.

Serological patterns	EIA	LIAISON®
IgG and IgM negative	205	205
IgG and/or IgM positive	56	83
IgG and/or IgM equivocal	39	12
Total	300	300

All the positive or equivocal samples were resolved by Western Blot analysis. The total number of performed Western Blot was 114 and 104 for EIA and LIAISON® assays respectively:

Western Blot agreement	Percentage positive results
EIA	80.7%
Liaison®	87.5%

Ease of use

* **Full automation**
* **Two-point recalibration** stable for 1 week
* **Controlled reagent** cooling and incubation conditions
* **Calibrators included**
* **Ready-to-use** reagent cartridge

Flexibility enables quick results

* **High throughput:**
  * Borrelia IgG: 90 results/hour
  * Borrelia IgM: 45 results/hour
* **Time to first result:**
  * Borrelia IgG, Borrelia IgM: 35 min
* **Stored master curve**
* **Little sample volume** 20 µL

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