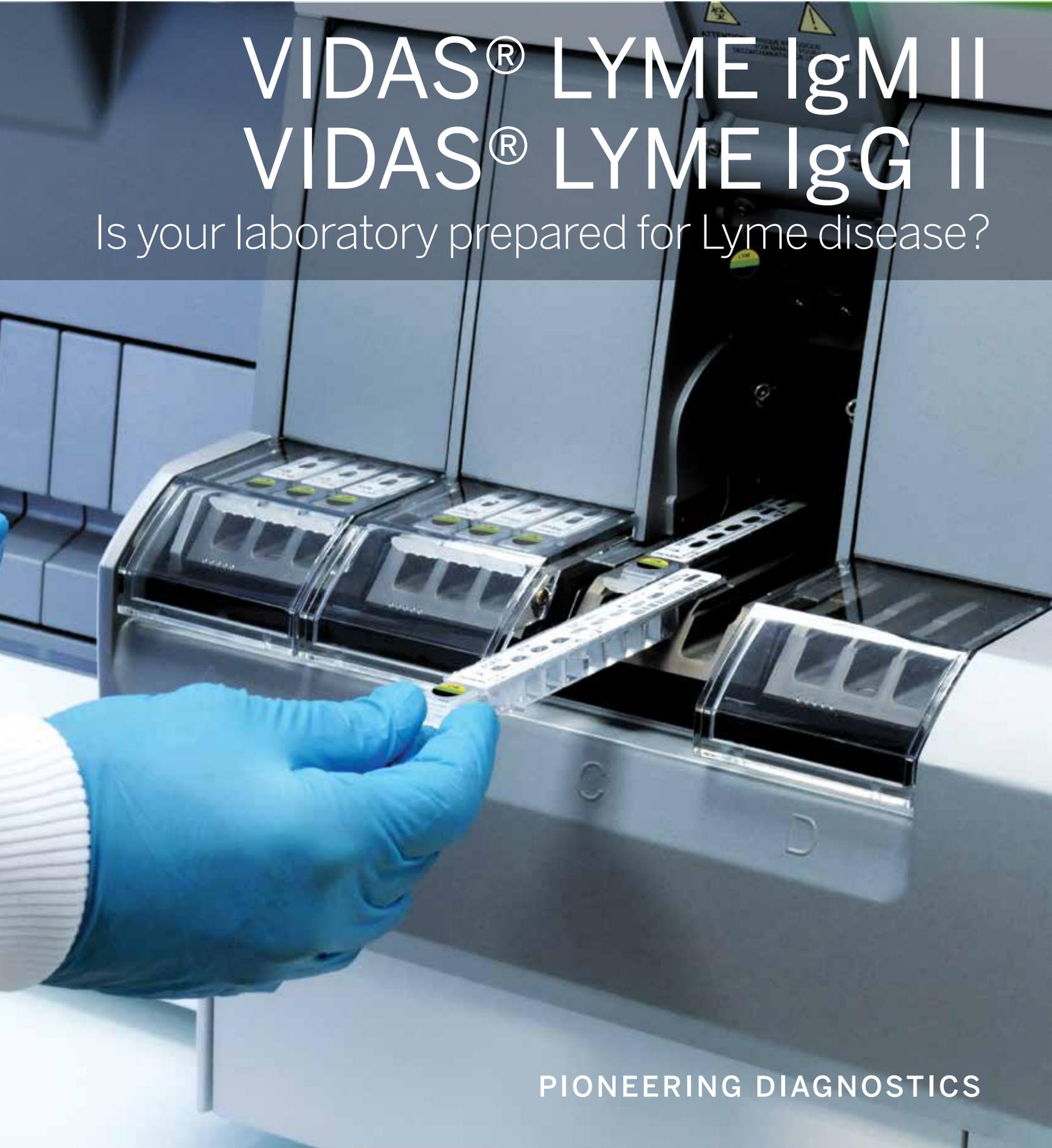




VIDAS[®] LYME IgM II VIDAS[®] LYME IgG II

Is your laboratory prepared for Lyme disease?



PIONEERING DIAGNOSTICS

VIDAS® Lyme IgM II

VIDAS® Lyme IgG II

HIGH SPECIFICITY AND SENSITIVITY

The VIDAS Lyme IgG II assay contains a combination of 3 recombinant chimeric *Borrelia burgdorferi sensu lato* proteins (VlsE, DbpA, and OspC).

- Outer surface proteins (OspC, DbpA, VlsE) play a major role in the immune response of the infected host. Additionally, all three antigens used in these assays have been shown to be immunogenic during human infection.⁵
 - OspC (Outer surface protein C) is essential to establish *Borrelia* infection, essentially produced *in vivo*.
 - DbpA (Decorin-binding protein A) outer surface protein produced by *Borrelia*, essentially *in vivo*.
 - VlsE (Variable major protein-like sequence), expressed *in vivo* presents a highly immunogenic conserved region, used for serodiagnosis.

“When using the LYM/LYG EIAs as a first-tier test followed by the C6 EIA as a second tier-test, it should be noted that the LYG EIA uses VlsE as one of three test antigens. VlsE is an immunogenic variable surface protein of *B. burgdorferi* that contains two invariable domains at each terminus, and a central domain that is composed of six variable and six invariable regions (IRs).^{2,3} C6 is the sixth invariable region (IR6) of the central domain of VlsE.”⁴

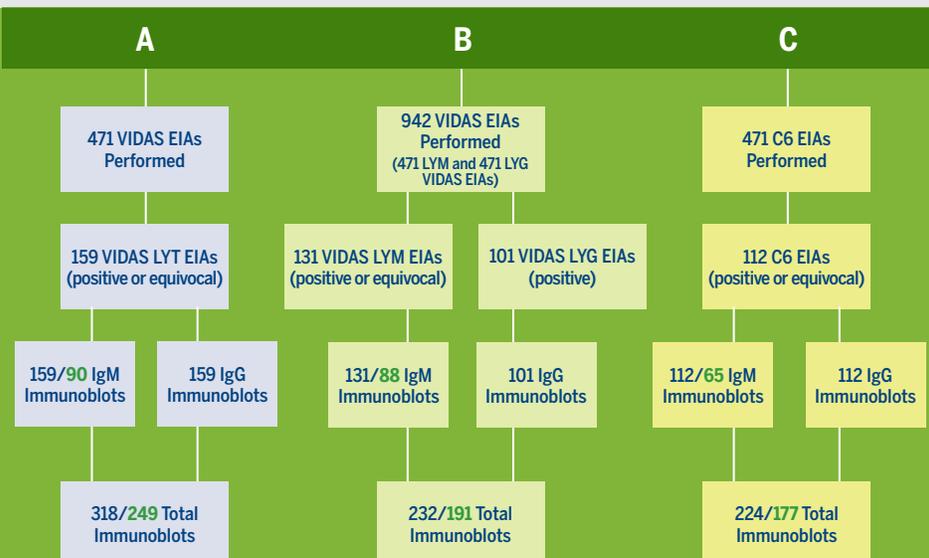
Less rework and clinically unnecessary confirmatory tests.⁵

Figure 1: CDC Confirmed Immunoblot Reduction

A - When the combined LYT EIA assay is used as a first-tier test, all samples that test positive or equivocal are reflexed to both IgM and IgG immunoblotting, for a total of 318 immunoblots needed to perform STTT.

B - When the dissociated LYM and LYG assays are used as first-tier tests, the samples that are positive or equivocal by LYM are reflexed to IgM immunoblotting, and the samples that are positive by LYG are reflexed to IgG immunoblotting. The numbers to the right, in bright green, take duration of illness into account for LYM testing, and only patients having ≤ 30 days of illness are tested by the LYM EIA and IgM immunoblotting. The total number of immunoblots needed for two-tiered testing using the dissociated LYM and LYG EIAs was 232 when duration of illness was not considered and 191 when duration of illness was considered.

C - When the C6 EIA assay is used as a first-tier test, all samples that test positive or equivocal are reflexed to both IgM and IgG immunoblotting, for a total of 224 immunoblots needed to perform STTT.





ADVANTAGES

Differentiated serological profile

- Facilitates classification of Lyme borreliosis: early or late/ chronic, active or immune
- Helps ensure patients receive rapid, optimized treatment depending on their stage of infection
- Potential to deduce information on disease progression (based on IgG and/or IgM positivity)⁵

Better patient management¹ and only patients with Lyme borreliosis are treated

- Innovative recombinant chimeric proteins (VlsE, DbpA, OspC) allowing detection of all main pathogenic *Borrelia* strains (*sensu stricto*, *afzelii*, *garinii*). The design of the chimeric protein constructs includes C6 (the VlsE invariant region IR6), which allows the VIDAS Lyme IgG II assay to provide high sensitivity and specificity and limit cross reactivity
- Low level of cross-reaction (syphilis, other infectious diseases)

Easy result interpretation

- No equivocal zone for VIDAS Lyme IgG II results
- Avoid unnecessary patient anxiety and additional testing

Streamlined workflow, rapid results

- Results in 27 minutes
- Calibration only once every 28 days
- Ease-of-use
- Single-dose tests

Cost effective^{5,6}

- Decreased number of total immunoblots that are needed for second-tier testing
- Reduction in costs associated with immunoblots
- Reduction in the level of specialized training that is required to properly perform an EIA as compared to immunoblotting





VIDAS[®] LYME IgM II

VIDAS[®] LYME IgG II

Differential diagnosis
in just 27 minutes

TECHNICAL SPECIFICATIONS

	VIDAS [®] LYME IgM II	VIDAS [®] LYME IgG II
Code	LYM	LYG
Reference	416436	417401
Tests/kit	60 tests	60 tests
Sample type	Plasma, serum	Plasma, serum
Sample volume	100 µl	100 µl
Calibration	1 level every 28 days	1 level every 28 days
Time to result	27 minutes	27 minutes
Results	Qualitative	Qualitative; no equivocal range

Patent pending no. PCT/FR2010/051787 and no. PCT/FR2010/051780
See package insert for more details

CPT Code: 86618
CPT Code Modifier: -59

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REFERENCES

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