



# Platelia™ Lyme IgM and IgG EIA

Highly sensitive and specific assays for accurate and precise screening of Lyme Borreliosis

## High Specificity

- Low cross reactivity with Syphilis
- IgM immuno-capture format

## High Sensitivity

- Improved detection of all disease stages
- Detection of human IgM and IgG antibodies to *Borrelia burgdorferi*
- Improved sensitivity by combining IgM and IgG results

## Enhanced Practicability

- Standardized protocols to run both assays in parallel
- Common reagents and incubation protocols

## Advantages for Your Laboratory

- Less confirmation testing necessary
- Better patient management
- Improved laboratory efficiency

**BIO-RAD**

## Platelia™ Lyme IgM and IgG Performance

Platelia™ Lyme assays demonstrate a high negative, positive and overall agreement with the CDC panel (*internal data*).

Agreement with Clinical Diagnosis <sup>1,4</sup>	Bio-Rad Platelia™ Lyme Assays <sup>2</sup>	Commercially Available		
		Lyme IgG and IgM Assays (Kit A, B)	Lyme Total Ig Assay (Kit C) <sup>3</sup>	Lyme Total Ig Assay (Kit D) <sup>2</sup>
IgM	74.4% (32/43)	63.6% (28/44)	Not applicable	Not applicable
IgG	69.8% (30/43)	63.6% (28/44)	Not applicable	Not applicable
Total Antibody (Overall Agreement) <sup>5</sup>	90.7% (39/43)	86.4% (38/44)	81.4% (35/43)	83.7% (36/43)
Total Antibody (Negative Agreement) <sup>5</sup>	80.0% (4/5)	80.0% (4/5)	100.0% (5/5)	60.0% (3/5)
Total Antibody (Positive Agreement) <sup>5</sup>	92.1% (35/38)	87.2% (34/39)	78.9% (30/38)	86.8% (33/38)

- 1 Equivocal samples considered as positive.
- 2 One sample not tested due to insufficient sample volume.
- 3 One sample not tested.
- 4 Combined result considered positive when sample is positive for IgM and/or IgG. Combined result considered equivocal when both IgM and IgG are equivocal, or IgM is equivocal with IgG negative, or IgM is negative with IgG equivocal. Combined result considered negative when sample is negative for both IgM and IgG.
- 5 Overall agreement, negative agreement and positive agreement for Total Antibody was calculated by combining results of IgM and IgG.

Results obtained on positive retrospective samples demonstrate excellent sensitivity of Platelia™ Lyme assays for both localized and disseminated stages of Lyme disease.

% Sensitivity	Platelia™ Lyme IgM	Platelia™ Lyme IgG	Platelia™ Lyme IgM and/or IgG <sup>2,3</sup>
Early Stage	85.0% (102/120)	59.2% (71/120)	90.8% (109/120)
Disseminated Stage	87.9% (29/33)	60.6% (20/33)	93.9% (31/33)
Late Stage	46.2% (6/13)	100.0% (13/13)	100.0% (13/13)
All Stages	82.5% (137/166)	62.7% (104/166)	92.2% (153/166)

- 1 Equivocal results were considered as positive for calculation of sensitivity.
- 2 Combined result considered positive when sample is positive for IgM and/or IgG. Combined result considered equivocal when both IgM and IgG are equivocal, or IgM is equivocal with IgG negative, or IgM is negative with IgG equivocal. Combined result considered negative when sample is negative for both IgM and IgG.
- 3 Dual positives have been included in the calculations only once.

### Ordering Information

**Catalog No. Description**

25296	Platelia™ Lyme IgM .....	96 tests
25297	Platelia™ Lyme IgG.....	96 tests



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