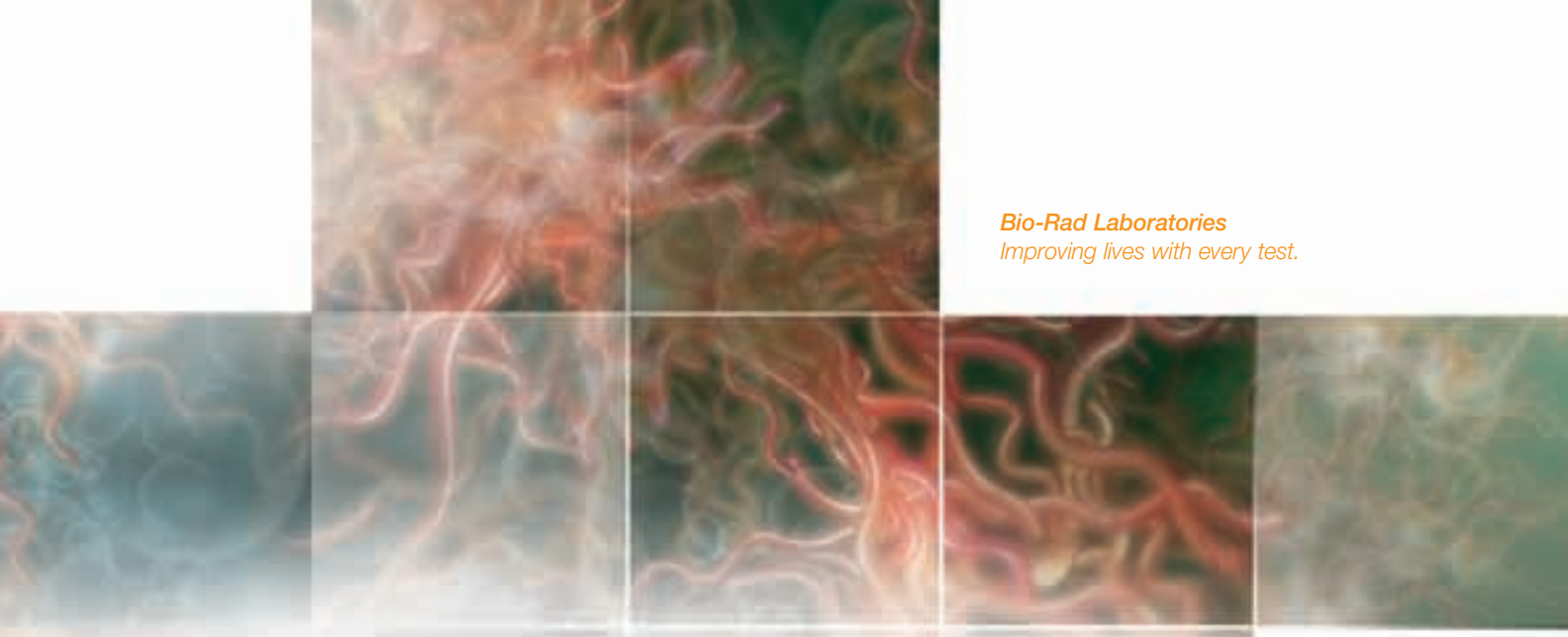

Bio-Rad Laboratories
Improving lives with every test.

Lyme Disease

Lyme EIA IgG/IgM/IgA

Lyme disease (Borreliosis) occurs in North America, Europe and Asia. The disease is transmitted through the bite of a tick infected by the spirochete, *Borrelia burgdorferi*, and presents with a variety of symptoms that may be confused with immune and inflammatory disorders.

Inflammation around the tick bite causes a skin lesion, erythema chronicum migrans (ECM), which is an early manifestation of the disease. ECM, the first stage of *Borrelia burgdorferi* disease, is also associated with neuralgic or cardiac symptoms (Stage 2) or arthritic symptoms (Stage 3). Persons of all ages and both genders are susceptible.

The Bio-Rad Lyme EIA microplate assay can be used as an aid in the diagnosis of Lyme disease through easy and rapid detection of IgG, IgM and IgA antibodies to B. burgdoferi. The diagnosis of Lyme disease is based primarily on clinical findings. When serological testing is indicated, the CDC recommends testing initially with a sensitive test first, such as ELISA or IFA, with follow up using the more specific Western Blot.

Improved assay sensitivity

The Bio-Rad Anti-Borrelia (Lyme) EIA combines purified *Borrelia burgdorferi* lysate and recombinant p39 protein as antigens.

Improved assay specificity

To improve assay specificity, serum is absorbed in a blocking solution containing *E.coli* proteins.

Convenient

- Ready-to-use reagents
- Rapid turnaround

Objective

- Microplate EIA format
- Qualitative and semi-quantitative detection

Simple

- 96-test kit
- Indirect EIA

Total Antibody Testing

- Detects *Borrelia burgdorferi* total antibodies (IgG, IgM and IgA) in serum

INFECTIOUS DISEASE TESTING

BIO-RAD

Lyme Disease Testing

The specificity of the Bio-Rad Anti-Borrelia (Lyme) Microplate EIA using 250 sera from asymptomatic blood donors collected from areas other than the upper Midwestern and Northeastern United States (hyperendemic regions) is 100% specific. Six samples (2.4%) tested borderline.

The specificity was also determined using sera from Lyme disease negative, symptomatic subjects (see Specificity table below). Because of the high frequency of false positive reactions with samples from syphilis patients, subjects suspected to have syphilis or related disorders must also be tested with a non-treponemal test (e.g. RPR) to rule out this cause.

Specificity — Lyme Disease Negative Patients

Sample Type	Nonreactive	Borderline	Reactive	Specificity
ANA +	37	1	0	100%
CMV IgM +	24	0	1	96%
Heterophile +	20	4	1	96%
RF +	23	1	1	96%
Syphilis +	0	1	11	8%
HIV +	15	0	0	100%

Sera from seventy-seven patients diagnosed with Lyme borreliosis were used to assess assay sensitivity. Diagnoses were based on epidemiological, clinical and serological criteria. These studies were conducted by two outside laboratories. The results are summarized in the Sensitivity table below.

Sensitivity — Diagnosed Lyme Disease Patients

Sample Type	Nonreactive	Borderline	Reactive	Sensitivity
Stage 1 (Early)	0	1	7	88%
Stage 2 (Neurological)	0	0	1	N/A
Stage 3 (Arthritis)	0	0	21	100%
Unknown Stage	0	0	47	100%

Ordering Information

Catalog No.	Description
32507	Bio-Rad Anti-Borrelia (Lyme) EIA..... 96 tests

BIO-RAD

Bio-Rad Laboratories

For further information, please contact the Bio-Rad office nearest you or visit our website at www.bio-rad.com/diagnostics.

Clinical Diagnostics Group

Website *www.bio-rad.com/diagnostics* ***U.S.*** *1-800-2-BIO-RAD* ***Australia*** *61-2-9914-2800* ***Austria*** *43-1-877-8901* ***Belgium*** *32-9-385-5511* ***Brazil*** *5521-3461-5202* ***Canada*** *1-514-334-4372* ***Czech Republic*** *420-2-41430532* ***China*** *86-21-64260808* ***Denmark*** *45-4452-1000* ***Finland*** *358-9-804-22-00* ***France*** *33-1-4795-6000* ***Germany*** *49-89-31884-0* ***Hong Kong*** *852-2789-3300* ***India*** *91-124-6398112* ***Israel*** *972-3-9514127* ***Italy*** *39-02-216091* ***Japan*** *81-3-5811-6290* ***Korea*** *82-2-3473-4460* ***Mexico*** *5255-5534-2552* ***The Netherlands*** *31-318-540666* ***New Zealand*** *64-9-415-2280* ***Norway*** *47-23-38-41-30* ***Poland*** *48-22-3319999* ***Portugal*** *351-21-472-7700* ***Russia*** *7-095-721-14-00* ***Singapore*** *65-6415-3188* ***South Africa*** *27-11-442-85-08* ***Spain*** *34-91-590-5200* ***Sweden*** *46-8-555-127-00* ***Switzerland*** *41-61-717-95-55* ***Thailand*** *662-651-8311* ***United Kingdom*** *44-208-328-2000*

06/05 DG05-082 J-106