

1 **S2: 48 Studies Included in the SR and a List of licensed tests for Lyme disease as of May 2015**

2 **48 Studies Included in the SR**

- 3 1. Avery RA, Frank G, Eppes SC. Diagnostic utility of *Borrelia burgdorferi* cerebrospinal fluid polymerase
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132 **List of licensed tests for Lyme disease as of May 2015**

Name in Tables	Test Name	Company	Description/ Target	SR Table	FDA approved	HCMDA approved
EIA						
	3M IGG Fastlyme(TM) Test	3M Company			yes	
	Bartels lyme disease IgM EIA	Baxter Diagnostics Inc.			yes	
Vidas	Vidas Lyme Screen II (IgM and IgG)	Biomerieux Vitek Inc.	Whole cell sonicate, objective reading.	T2, T3, T5	yes	yes
BION Borrelia Burgdorferi Antigen Substrate Slide	BION Borrelia Burgdorferi Antigen Substrate Slide	MBL international	Whole-cell sonicated B. burgdorferi B31. Semi-quantitative.	T6	yes	
	Platelia® Lyme IgM /IgG	Bio-Rad Laboratories	Whole-cell sonicated B. burgdorferi B31 IgG and IgM. Objective reading.		yes	
	Boston Biomedica Inc. Borrelia burgdorferi IgM/ IgG	Boston Biomedica Inc.			yes	
Cambridge	Human Lyme EIA for the detect of antibodies	Cambridge Bioscience Corp.	Whole-cell sonicated B. burgdorferi B31 IgG and IgM. Objective reading.	T2, T6	removed	
	Prevue™ <i>Borrelia burgdorferi</i> antibody detection assay	Chembio Diagnostic Systems Inc.	Prevue™ <i>Borrelia burgdorferi</i> antibody detection assay uses recombinant antigens: OspA, OspB, OspC (3 types), p 93 and flagellin. Objective reading.		yes	
	IS <i>Borrelia burgdorferi</i> IgG/ IgM ELISA test system	Columbia Bioscience Inc.			yes	
	Lyme IgG/IgM ELISA	Diagnostic Automation	Whole-cell sonicated B. burgdorferi B31 IgG and IgM. Objective reading.			yes
	Lyme-check™ test kit	Diagnostic Technology Inc.			yes	
	Lyme Disease microassay (IgM/IgG)	Diamedix corp.			yes	
Liason	Liason Borrelia IgG /IgM assay model 310870 (CLIA)	Diasorin	chemiluminescence assay, quantitative determination IgG=VlsE target, IgM= two recombinant antigens OspC and	T2, T3, T6		yes

Anti-B. burgdorferi VlsE IgG	Euroimmun	VlsE. Objective reading Antigens: extract of Borrelia burgdorferi sensu stricto, Borrelia garinii and Borrelia afzelii (whole antigen) / recombinant VlsE from Borrelia burgdorferi sensu stricto (IgG). Objective reading	yes
Anti-Borrelia VlsE IgG	Euroimmun	Antigens: extract of Borrelia burgdorferi sensu stricto, Borrelia garinii and Borrelia afzelii (whole antigen) / recombinant VlsE from Borrelia burgdorferi sensu stricto (IgG). Objective reading	yes
Lyme Screen IgG/IgM	Euroimmun	Recombinant VlsE from Borrelia burgdorferi sensu stricto and Borrelia OspC. Semiquantitative. Objective reading	yes
CSF - Anti-Borrelia VlsE IgM/ IgG	Euroimmun	Whole antigen, SDS extract of Borrelia burgdorferi sensu stricto, B. garinii and B. afzelii plus recombinant VlsE of B. burgdorferi sensu stricto.	yes
Anti-Borrelia Select IgM/ IgG	Euroimmun	Highly specific recombinant antigens from different human pathogenic Borrelia strains are used as the antigen. The test includes VlsE. Objective Reading.	yes
Lyme IgM ELISA test	Gull laboratories Inc.	Whole cell sonicate B. burgdorferi (JD1 strain)	yes
Lyme Disease ELISA (IgG)	Hillcrest Biologicals		yes
Lyme disease IFA (IgG/ IgM)	Hillcrest Biologicals		yes
Borrelia + VlsE IgG	IBL International	Sandwich ELISA IgG= mixed antigens for B. burgdorferi, B. garinii and B. afzelii combined	yes

			with a recombinant VlsE antigen.			
	Borrelia 14kDa & OspC IgM	IBL International	Sandwich ELISA IgM= recombinant 14kDa and native OspC (from B. afzelii).			Yes
Immunetics C6	Immunetics® C6 <i>B. burgdorferi</i> ELISA™ kit	Immunetics®	Recombinant protein. Objective reading.	T2, T3, T6	yes	yes
	Quanta Lite® Lyme <i>B. burgdorferi</i> IgG/IgM ELISA kit	Inova diagnostics Inc.			yes	
MarDx Lyme disease EIA (IgM/IgG) test system	MARDX Lyme disease EIA (IgG & IgM) test system	MARDX diagnostics Inc.	Whole cell sonicate B. burgdorferi (Strain B 31), objective reading	T3, T6	yes	yes
	MARDX Lyme disease IgG/IgM IFA test system	MARDX diagnostics Inc.	Whole cell sonicate B. burgdorferi (strain B31). objective reading		yes	
	<i>Borrelia burgdorferi</i> IgM antibody test system	Medical Diagnostic Technologies Inc.			yes	
	<i>Borrelia burgdorferi</i> polyval IgG/IgM antibody test	Medical diagnostic technologies Inc.			yes	
	RecomWell Borrelia IgM/ IgG	Mikrogen	Immunodominant antigens of B. burgdorferi sensu stricto, B. garinii and B. afzelii. IgM: OspC, p41/internal, VlsE and IgG: p100, OspC, VlsE, p18			yes
	Classic B. burgdorferi IgG/ IgM	Serion	Qualitative and quantitative immunoassays. Mixture of native antigens from B. afzelii and B. garinii and recombinant VlsE.			yes
	<i>Borrelia burgdorferi</i> IgG/ IgM ELISA test system	Trinity Biotech USA	Whole cell sonicate of B. burgdorferi (strain B31)		yes	
	Lyme-Spot IF kit	Vitek systems Inc.			yes	
Wampole	<i>Borrelia burgdorferi</i> IgG/IgM ELISA test system	Wampole laboratories	Whole cell sonicate. Objective reading.	T2, T3, T5	yes	
	FIAX test kit for Lyme Disease antibodies (IgG/IgM)	Whittaker Bioproducts Inc.			yes	
Lyme STAT test	Lyme STAT M or G test kit (IgG/IgM)	Whittaker Bioproducts Inc.	Whole cell sonicate. Subjective	T3, T6	yes	

kit			reading.			
Zeus AtheNA	Athena multi-lyte borrelia VlsE-1/PEPC10 plus test system	Zeus Scientific Inc.	VlsE-1/ PEPC10- recombinant multiplex IgG. Objective reading	T2	yes	
	IFA test for antibodies to <i>Borrelia burgdorferi</i>	Zeus Scientific Inc.	Semi-quantitative. Whole cell sonicate, <i>B. burgdorferi</i> (B31 Strain).		yes	Yes
Zeus ELISA	Lyme ELISA test system (IgG/IgM)	Zeus Scientific Inc.	Whole cell sonicate, <i>B. burgdorferi</i> (B31 Strain). Objective Reading.	T2	yes	yes
	Zeus ELISA Borrelia VlsE-1/PEPC10 IgG/IgM test system	Zeus Scientific Inc.	Inactivated VlsE-1 and pepC10 antigens. Objective reading		yes	yes
Westernblot						
BBI Bb IgM or IgG Western Blot Test Kit	BBI-Biotech research laboratories <i>B. burgdorferi</i> IgM Western blot kit	Boston Biomedica Inc.	Purified antigen. Subjective reading	T4, T6	yes	
Cambridge Biotech Human Lyme IgG /IgM Western Blot	Cambridge Biotech Human Lyme IgG / IgM western blot (90111/ 90112)	Cambridge Biotech Corp. / Calypte Biomedical Corp.		T6	yes	
	Human Lyme IgM/IgG western blot kit	Cambridge Diagnostics Ireland Ltd.			yes	
	Anti- <i>B. burgdorferi</i> US EuroLine IgG /IgM	Euroimmun	Whole antigen, SDS extract of <i>B. burgdorferi sensu stricto</i>			Yes
	Anti- <i>B. afzelii</i> IgG	Euroimmun	Whole antigen, SDS extract of <i>B. afzelii</i>			Yes
	Anti- <i>B. garinii</i> IgG	Euroimmun	Whole antigen, SDS extract of or <i>B. garinii</i>			yes
ImmunoDOT Borrelia Dot Blot IgG/IgM Test (GenBio)	ImmunoDOT Borrelia dot blot G or M test	GenBio	whole <i>B. burgdorferi</i> antigens and four specific proteins: a high molecular weight protein (HMW), flagellin, a 39 kD protein (p39/ BmpA), and outer surface protein C (OspC). Subjective reading.	T4, T6	yes	
Immunowell Borrelia (Lyme) test	Immunowell <i>Borrelia</i> (Lyme) test	GenBio	Whole cell <i>B. burgdorferi</i>	T6	yes	

	<i>Borrelia burgdorferi</i> B31 IgM/IgG line blot test	Gold Standard diagnostics	Target proteins IgG=p83/93/100 (Late LD) Oms66 (p66), OppA-2 (p58), Heat Shock (p45), Flagellin (p41), BmpA (p39). OspA (p31), (p30, p28, p18), OspC (p23). IgM= flagellin (p41), and OspC (p23). Objective reading.		yes	
	Qualicode <i>B. burgdorferi</i> gG/IgM western blot kit models DK-C052-024/DK-C062-024	Immunitics®			yes	
Marblot	Mardx Lyme Disease (IgM/IgG) Marblot strip test system	Mardx Diagnostics Inc.	Purified antigens/ Subjective reading.	T2, T4, T5, T6	yes	yes
	RecomLine <i>Borrelia</i> IgM/ IgG	Mikrogen	Detects antibodies to <i>B. burgdorferi</i> , <i>B. garinii</i> , <i>B. afzelii</i> , <i>B. spielmanii</i> and <i>B. bavariensis</i> targeting VlsE, OspC and p18 (DbpA), p58 (<i>B. garinii</i>), p39 (<i>B. afzelii</i>), OspA (<i>B. afzelii</i>), p100 (<i>B. afzelii</i>), p41 (<i>B. burgdorferi</i> ss)			yes
MRL diagnostics: Lyme Disease Bb genogroup 1 WB IgG or IgM	Lyme disease <i>B. burgdorferi</i> genotype 1 western blot IgG/IgM (WB0400G/WB0400M)	MRL Diagnostics		T5	yes	
Virablots	Viramed biotech <i>Borrelia</i> B31 IgM/IgG Virablots	Viramed Biotech Ag	Purified antigen/ Subjective reading.	T2, T4	yes	
	Viramed Biotech AG <i>Borrelia</i> B31 IgG /IgM Virastripe® Model V-BBSGUS	Viramed Biotech Ag	Native, purified antigens <i>B. burgdorferi</i> (strain B31), Subjective reading.		yes	
	<i>Borrelia burgdorferi</i> IgG or IgM western blot test system	Zeus Scientific Inc.			yes	
PCR						
	<i>Borrelia</i> Burgdorferi Primer Pair	Focus Diagnostics				