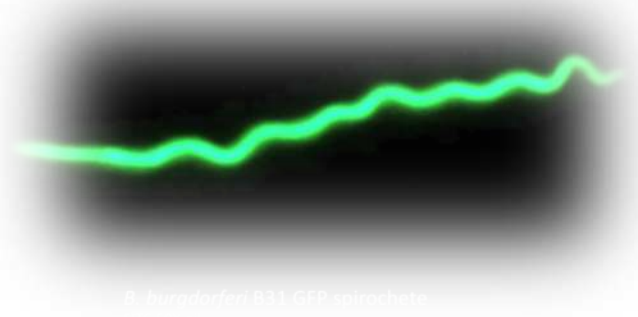
LYME HASTALIĞI TANISI: DOĞRULAR ve YANLIŞLAR

Dr. A. Arzu Sayıner

Tıbbi Mikrobiyoloji A.D.

Çok Boyutlu Enfeksiyonlar ve Lyme Hastalığı Araştırma ve Uygulama Merkezi

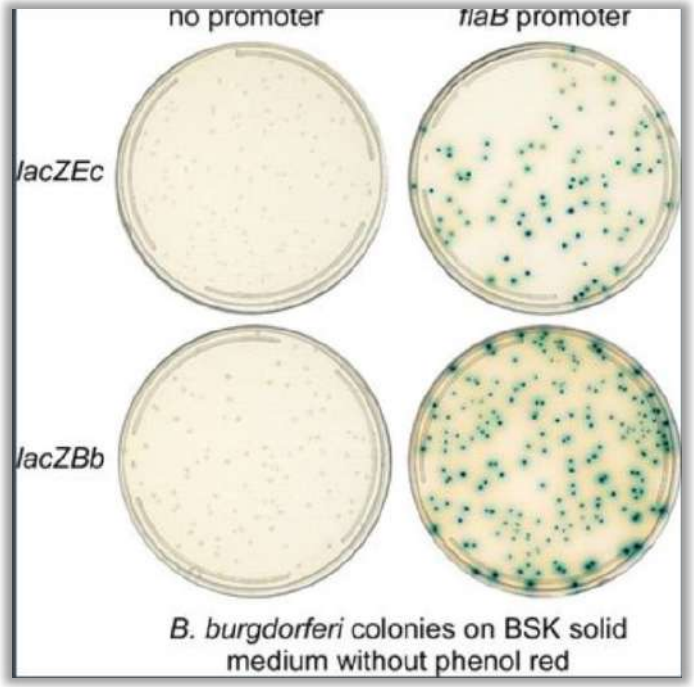
Dokuz Eylül Üniversitesi Tıp Fakültesi



Mikrobiyolojik Tanı

- Kültür
  - Barbour-Stoenner-Kelly (BSK) besiyeri → 12 hafta
  - Konfirmasyon testleri

  Rutin tanıda önerilmez.
- Antijen saptama – İdrar testi
- Antikor saptama
  - Erken dönemde ($\leq 14\ g\ddot{u}n$) → duyarlılık düşük
  - Geç dönemde %75-100
- Nükleik asid testi - PCR



B. burgdorferi colonies on BSK solid medium without phenol red

Akut dönem enfeksiyon

- Endemik bölgede kene ısırığı öyküsü sonrası tipik eritema migrans - - Klinik tanı ve direkt tedavi - test gerekli değil.
- Atipik deri lezyonu olan hastalarda
  - Antikor testi
    - İlk test negatif ise 2-3 hafta sonra test tekrarı
  - Dokuda veya kanda PCR veya kültür önerilmemektedir.

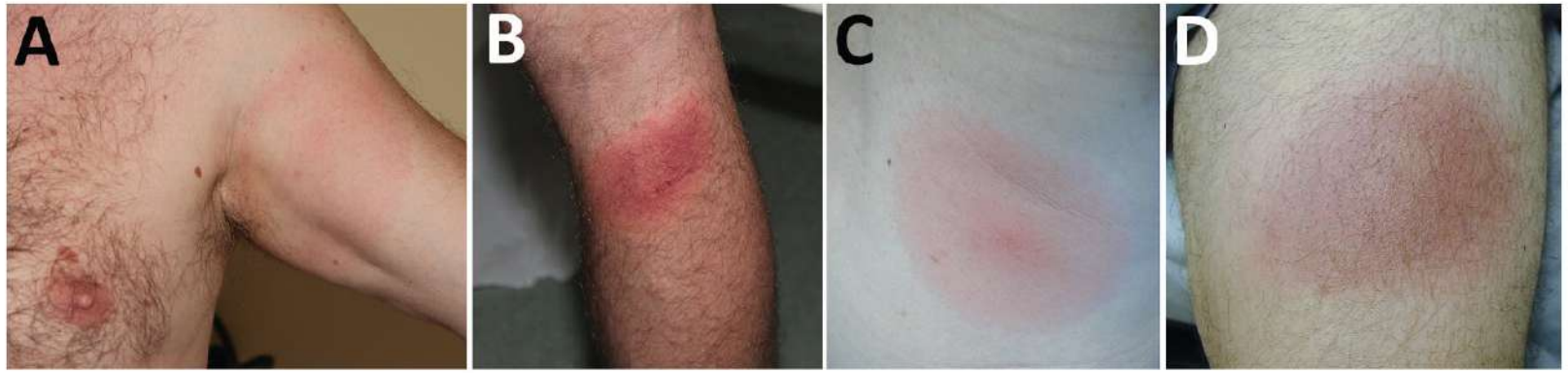


Figure 1. Erythema migrans skin lesions from patients in Europe (A, B) and the United States (C, D)

Neuroborreliosis

- Serum antikor testi
- Serum ve BOS → antikor indeksi
  - Duyarlılık %60-80
  - Tedavi sonrası yıllarca yüksek kalabilir.
- BOS'da veya serumda PCR veya kültür önerilmemektedir.
  - Erken dönem BOS'da PCR duyarlılığı %5-30
    - Geç dönem BOS'da PCR duyarlılığı ⬇
  - Serumda PCR duyarlılık %1-28
- BOS'da CXCL13 – kemokin biyomarker
  - Tanıda non-spesifik, standardize değil
  - Tedavi başarısını izlemede anlamlı olabilir.

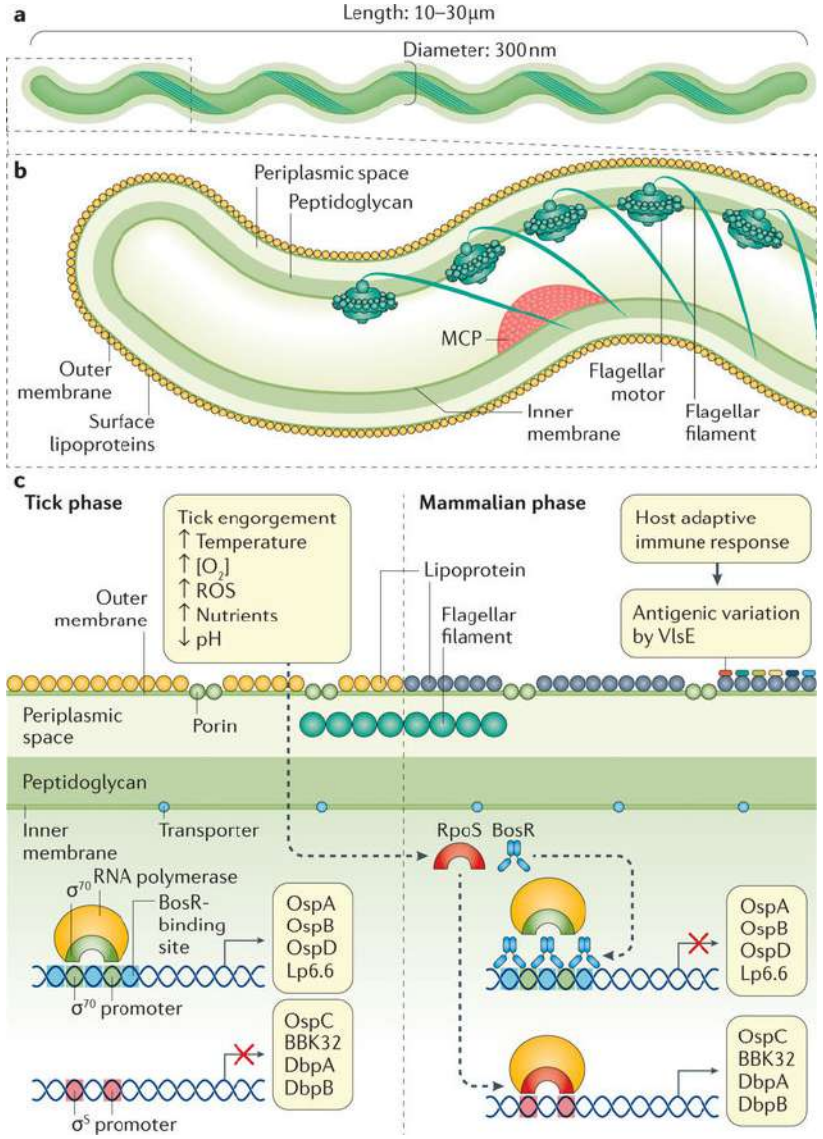
Lyme Artriti

- Serum antikor testi
  - Seropozitif olguda ek inceleme gereksinimi varsa sinoviyal sıvıda/biyopside PCR
    - Duyarlılık %80'e ulaşabilir.

Antikor testleri

- Tam bakteri lizatı
- Saflaştırılmış antijen
- Rekombinant veya sentetik antijen (üçüncü kuşak testler)
  - OspC, p100, p18, p41, VlsE-C6

Lyme şüphesi veya tanısının yanısıra ateş, trombositopeni, nötropeni, anemi olan olgularda babezyoz ve anaplozmoz incelenmesi önerilir.



Protein ekspresyonu

- Kenede ve memelide farklı
  - Memelide dokular arası fark
  - İmmun yanıta bağlı fark
- Kültürde ve konakta farklı
- Türler, kökenler arası farklı
  - Özellikle OspC
- Dış membran proteinleri
  - Beslenmemiş kene: OspA, OspB
  - Kan emmiş kene ve memeliye geçiş : OspC
  - Konak immun yanıtı
    - Immunsüprese konakta persistan OspC ekspresyonu
- Yüzey lipoproteinleri
  - Geç dönem enfeksiyon: VlsE

Lyme – Antikor Testleri

- Enfeksiyondan haftalar – aylar sonra, deri dışı bulguların olduğu dönemde duyarlı ve güvenilir tanı
- IgG (-) → tedavi almamış olgularda tanıyı dışlama kriteri
- Erken dönem → Negatiflik
  - İlk hafta içinde %20 (+)
  - 4. haftada %86 (+)
- Güvenilir tanı için: Antikor testleri + kene öyküsü + epidemiyoloji + klinik

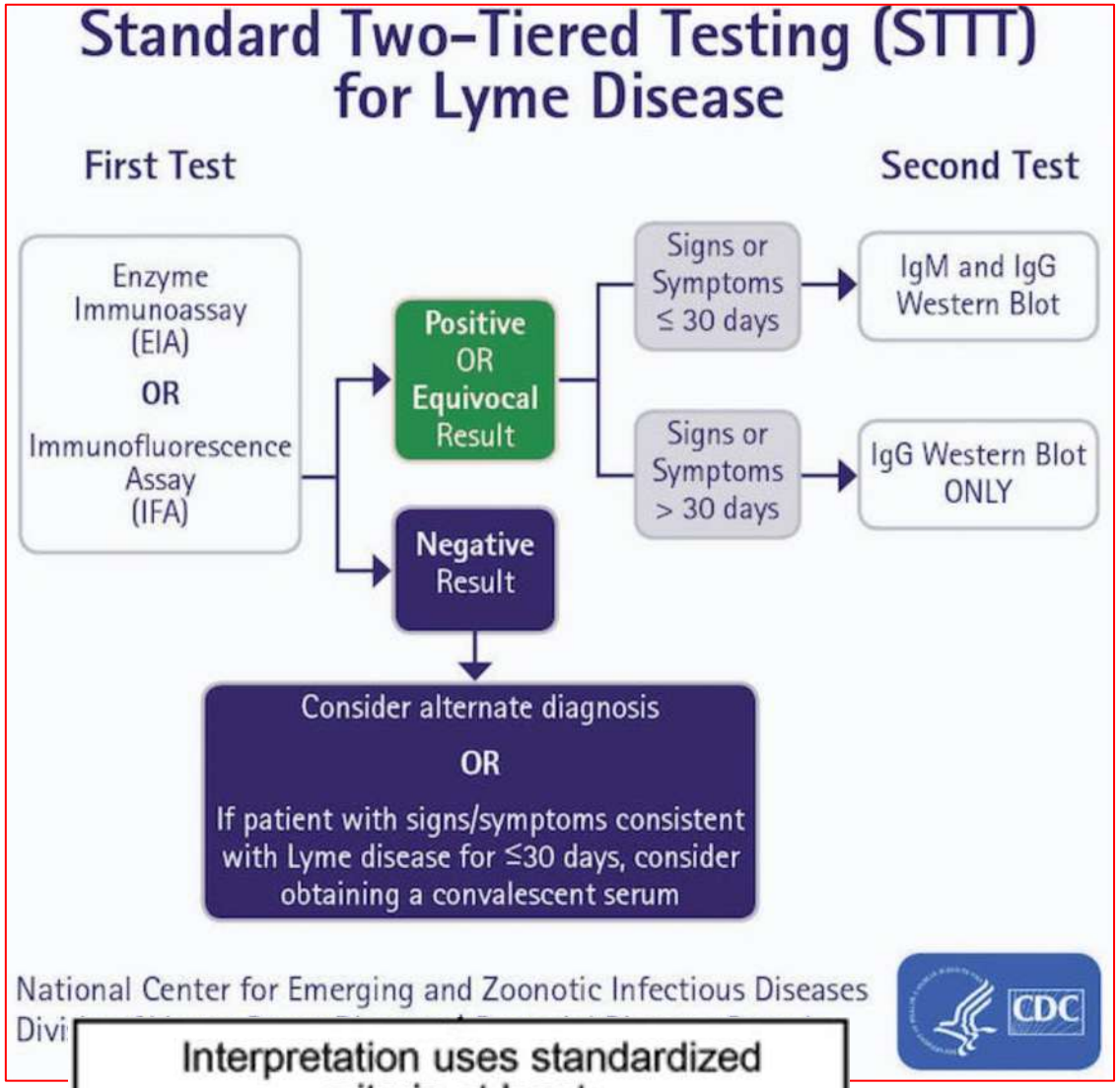
İki basamaklı tanı

Duyarlılık %70-100, Özgüllük >%95

- Standart protokol
  - EIA / IFA → IgM / IgG immunblot
- Modifiye protokol
  - İki EIA eş zamanlı veya peşisıra

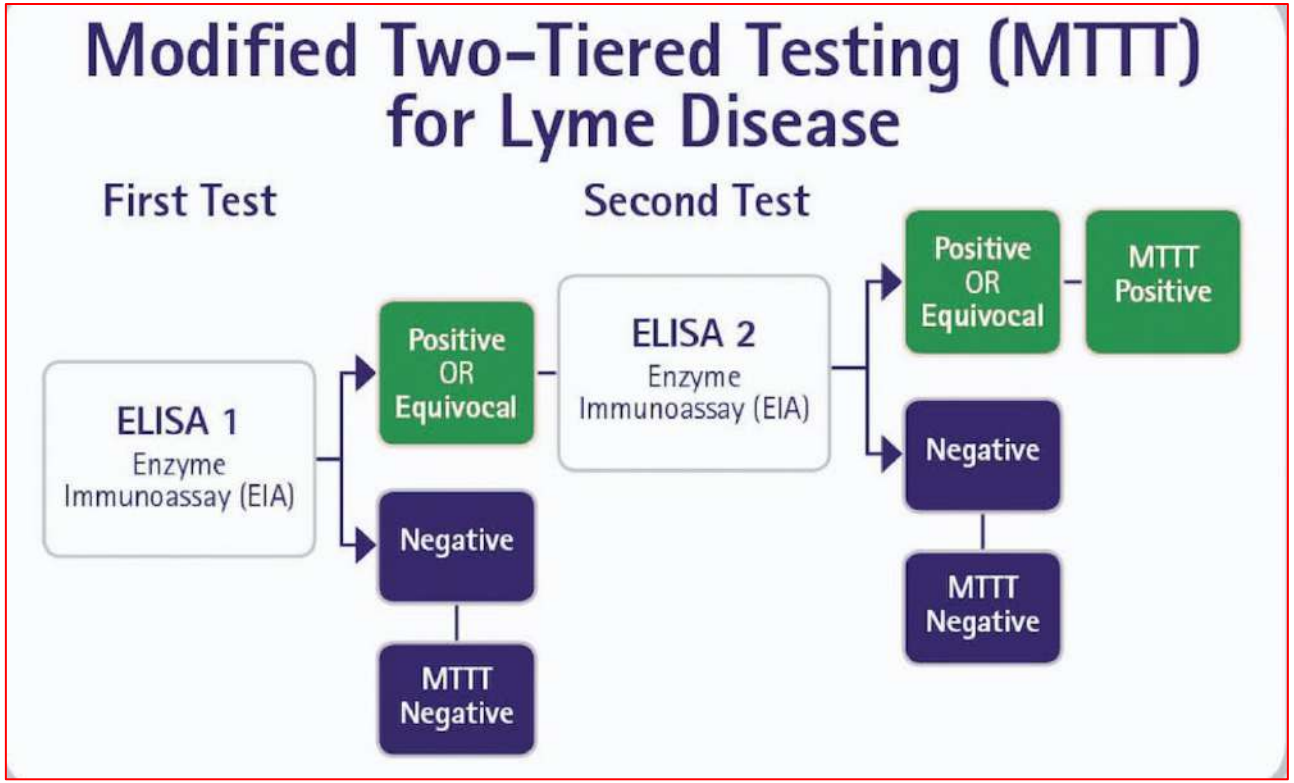
Antikor testlerinde sorunlar

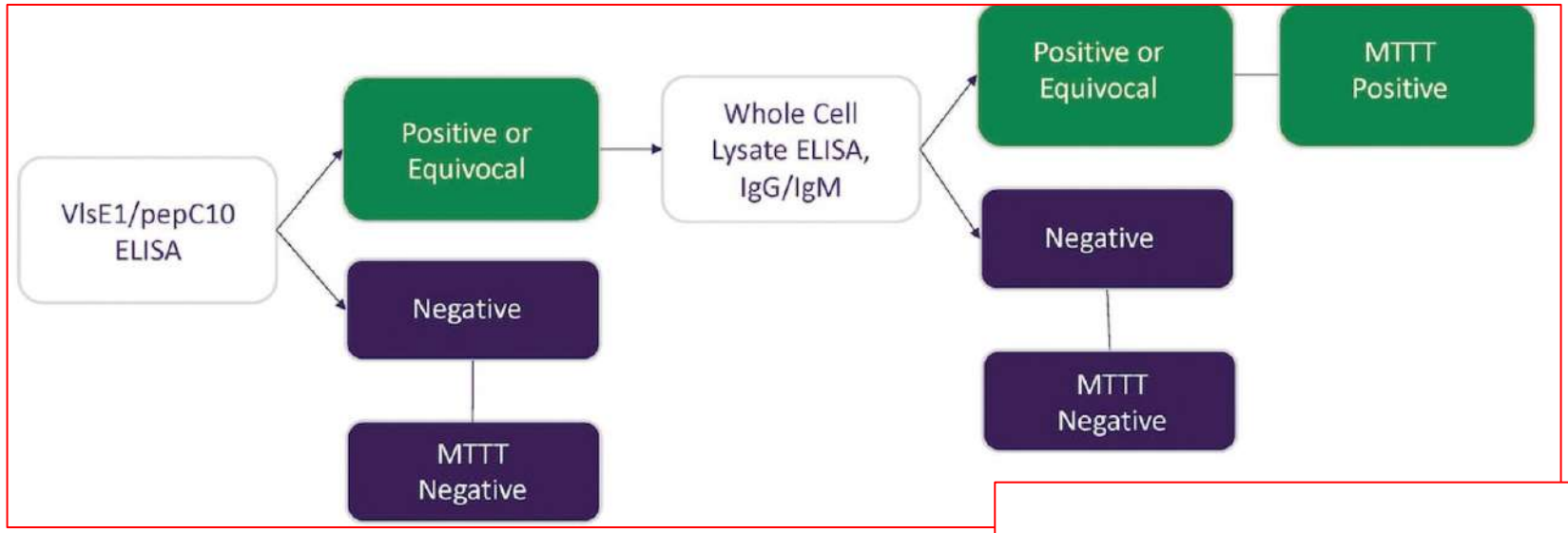
- IgM ve IgG pozitifliği → yıllarca sürebilir
  - Enfeksiyonun zamanının belirlenememesi
  - Reenfeksiyonları, eski enfeksiyonlardan ayırmada sorun
- Yalancı pozitiflikler
  - Otoimmün hastalıklar
  - Diğer enfeksiyonlar

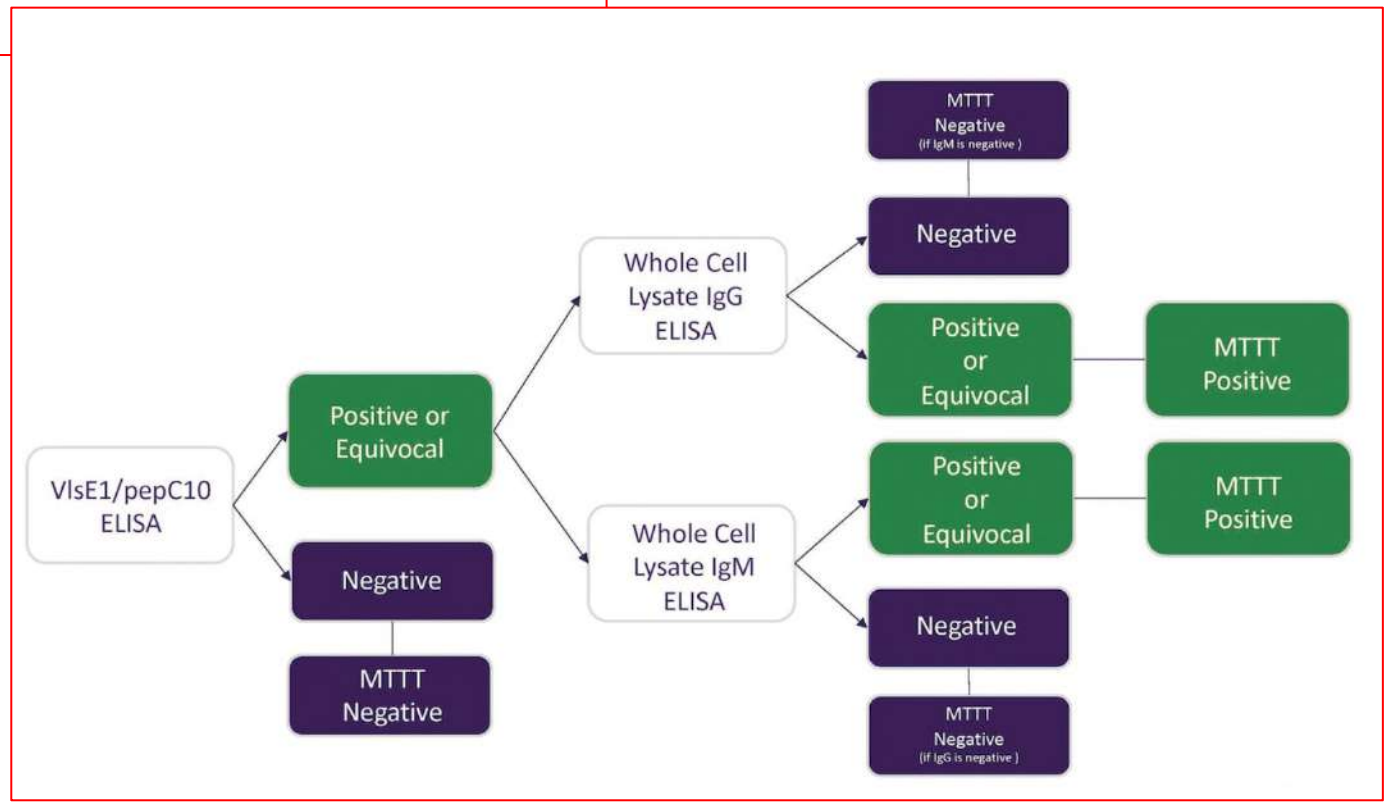


Interpretation uses standardized criteria at least:

2 of 3 bands for a positive IgM WB
5 of 10 bands for a positive IgG WB




VlsE1/pepC10 ELISA
Positive or Equivocal
Negative
MTTT Negative
Whole Cell Lysate ELISA, IgG/IgM
Positive or Equivocal
MTTT Positive
Negative
MTTT Negative


VlsE1/pepC10 ELISA
Positive or Equivocal
Negative
MTTT Negative
Whole Cell Lysate IgG ELISA
Negative
Positive or Equivocal
MTTT Positive
MTTT Negative (if IgM is negative)
Whole Cell Lysate IgM ELISA
Positive or Equivocal
MTTT Positive
Negative
MTTT Negative (if IgG is negative)

FDA NEWS RELEASE

FDA clears new indications for existing Lyme disease tests that may help streamline diagnoses

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For Immediate Release: July 29, 2019

Today, the U.S. Food and Drug Administration cleared for marketing four previously cleared tests with new indications to aid in the diagnosis of Lyme disease. The tests cleared today are the first time that a test has been indicated to follow a new testing paradigm in which two tests called enzyme immunoassays (EIA) are run concurrently or sequentially, rather than the current two-step process in which a separate protein test called a Western Blot must be run after the initial EIA test.

The FDA reviewed data from clinical studies of the ZEUS ELISA Borrelia VlsE1/pepC10 IgG/IgM Test System, ZEUS ELISA Borrelia burgdorferi IgG/IgM Test System, ZEUS ELISA Borrelia burgdorferi IgM Test System, and the ZEUS ELISA Borrelia burgdorferi IgG Test System that showed this alternative approach, referred to as a modified two-tier test, is as accurate as current methods for detecting antibodies for assessing exposure to Borrelia burgdorferi, the causative agent of Lyme disease, over current methods.

accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm

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70 records returned meeting your search criteria - ***Lyme***

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Device Name	Company	Date Approved	Device or Consumer Information/Instructions
LIAISON Lyme IgM, LIAISON Lyme IgM Control Set, LIAISON Lyme Total Antibody Plus	DiaSorin Inc.	Feb 18, 2021	K202573
LIAISON Lyme IgG, LIAISON Lyme IgG Control Set, LIAISON Lyme Total Antibody Plus	DiaSorin Inc.	Feb 18, 2021	K202574
LIAISON Lyme Total Antibody Plus, LIAISON Lyme Total Antibody Plus Control Set	DiaSorin Inc.	Jan 29, 2020	K193051
Interlude Rolled Tampons In Plastic Applicator	ALBAAD Fem	Oct 07, 2019	K191431
BioPlex 2200 Lyme Total	Bio-Rad Laboratories	Mar 12, 2019	K183446
Interlude 100% Cotton Tampon	ALBAAD Fem	Nov 02, 2018	K181911

Table 1. Lyme disease in the United States and Europe

Variable	United States	Europe
Tick vector	*Ixodes scapularis*, *I. pacificus*	*I. ricinus*, *I. persulcatus*
Lyme borrelia	Mostly *Borrelia burgdorferi* sensu stricto; *B. mayonii* may occur in the upper midwestern United States	Mostly *B. afzelii* and *B. garinii*, but several other species cause human disease, including *B. burgdorferi* s.s., *B. bavariensis, B. spielmanii, and B. lusitaniae*
Speed of tick transmission of Lyme borrelia	Rarely before 36 h	*I. ricinus* ticks may transmit *B. afzelii* within 24 h
Predominant patient sex	Male patients account for 56% of reported cases during 2001–2018; no manifestation is predominant among female patients	Most cases of erythema migrans and acrodermatitis chronica atrophicans occur in women; neuroborreliosis and arthritis are predominant in men
Coinfections	Risk depends on the geographic area; the most common co-infections are anaplasmosis and babesiosis.	Risk depends on the geographic area; the most common co-infection is tick-borne encephalitis

Avrupa:

İlk basamak testte kullanılan ag: VlsE protein (C6 korunmuş epitope) + diğer VlsE epitopları + OspC (pepC10)

ABD:

Borrelia burgdorferi B31 suşuna ait antikorlar

Etken: Borrelia burgdorferi sensu lato (s.l.)

B. burgdorferi sensu stricto,

B. afzelii,

B. garinii,

B. bavariensis

B. spielmanii

Marques, EID,2021

Lyme – Antikor dışı tanı testleri

- Kültür
  - Akut dönem deri lezyonu - duyarlılık %40-60
- Nükleik asid testleri
  - Akut dönem
    - Deri lezyonu (min 2 mm çap, lezyon kenarı) - duyarlılık %80
    - Plazma – duyarlılık %30-50
  - Artrit → Duyarlılık %40-90
    - Tedavi sonrası da dokuda DNA saptanabilir.
  - İki basamaklı antikor testleri pozitif olduğunda ek test olarak kullanım önerilir
- Antijen saptama testleri
  - İdrarda OspA ag → enfeksiyonun aktivitesi ile ilişkili

- Akut dönem enfeksiyonda tanı testlerinin hiçbiri güvenilir değil, klinik tanı önerilir.
- PCR sorunlar
  - Onaylı, valide edilmiş, standart testlerin bulunmaması
  - Canlı – ölü bakteri ayrımı yapılamaması → aktif enfeksiyon kanıtı değil.

Open Forum Infectious Diseases

BRIEF REPORT

Modified Two-Tiered Testing Enzyme Immunoassay Algorithm for Serologic Diagnosis of Lyme Disease

Farhan Khan,[1,2] Ziyad Allehebi,[1,2] Yahya Shabi,[1,2] Ian Davis,[1,2] Jason LeBlanc,[1,2] Robbin Lindsay,[3] and Todd Hatchette[1,2]

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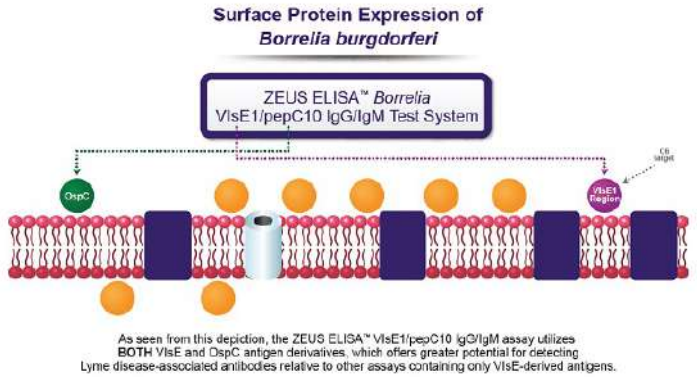
The modified 2-tier testing algorithm (MTTT) for Lyme disease (LD) has been approved by the US Food and Drug Administration. In this study, we show that the MTTT detected 28% more cases of early infection compared with the standard 2-tier algorithm while retaining high specificity in a region with a high incidence of LD.

Keywords. *Borrelia burgdorferi*; diagnostics; Lyme disease; modified two-tiered testing; serology.



Modifiye şema:

1. basamak → OspC (pepC10) / VlsE EIA total antikor
2. basamak → WCS EIA total antikor

Standart şema:

EUROIMMUN Anti-Borrelia burgdorferi WB (IgG) ve
EUROIMMUN Anti-Borrelia EUROLINE-RN-AT-adv (IgM).

Yalancı pozitiflik: 2/10 sifiliz hastası

ANA ve EBV-IgM pozitif örneklerde sorun saptanmamış

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RESEARCH A

The Performance of Nine Commercial Serological Screening Assays for the Diagnosis of Lyme Borreliosis: a Multicenter Modified Two-Gate Design Study

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ABSTRACT In this retrospective study, the performance of nine serological screening assays for Lyme borreliosis (LB) diagnostics was evaluated using a study population of LB cases and controls. Sera derived from 74 well-defined LB cases and 122 controls were included. The LB cases were diagnosed with erythema migrans (EM; n = 11), Lyme neuroborreliosis (LNB; n = 35), Lyme arthritis (LA; n = 20), or acrodermatitis chronica atrophicans (ACA; n = 8). Controls comprised 74 age- and gender-matched healthy individuals and 48 patients with other diseases with anticipated high rates of cross-reactivity. The assays under evaluation were selected based on a literature review and expected continued availability with CE marking under the new *in vitro* diagnostic regulation (European Union) 2017/746. The overall sensitivity (IgG and IgM results combined) among LB cases ranged between 54.5% (6 of 11) and 90.9% (10 of 11) for EM patients and between 97.1% (34 of 35) and 100% for patients with LNB, LA, and ACA. The positivity rate ranged between 8.1% (6 of 74) and 29.7% (22 of 74) among the healthy controls and between 22.9% (11 of 48) and 64.6% (31 of 48) among the cross-reactivity controls. The IgM results were more heterogeneous than the IgG and IgM/IgG results and did not contribute to the overall sensitivity but substantially increased the positivity rates among the controls. In conclusion, all evaluated *Borrelia* serological screening assays performed comparably with respect to early- and late-disseminated LB. The addition of an IgM assay to the screening of *Borrelia*-specific IgG antibodies had no added value for the diagnosis of Lyme borreliosis.

Editor Catherine Ayn Brissette, University North Dakota

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Eritema migrans grubu
IgM ve IgG: %54.5-90.9

Diğer klinik tablolar grubu
IgM ve IgG: %97.1-100

TABLE 2 Sensitivity and positivity rates of *Borrelia* serological screening assays[a]

	Sensitivity (%)					Positivity rate (%)	
Assay	All LB cases (n = 74)	EM (n = 11)	LNB (n = 35)	LA (n = 20)	ACA (n = 8)	Healthy controls (n = 74)	Cross-reactivity controls (n = 48)
IgM assays							
DRG IgM	45.9	36.4	68.6	25.0	12.5	10.8	35.4
Euroimmun IgM	55.4	18.2	68.6	55.0	50.0	6.8	37.5
Liaison IgM	51.4	36.4	68.6	35.0	37.5	8.1	33.3
NovaLisa IgM	55.4	45.5	77.1	30.0	37.5	23.0	41.7
Serion IgM	77.0	54.5	91.4	65.0	75.0	21.6	60.4
VirClia IgM	45.9	18.2	71.4	30.0	12.5	8.1	29.2
IgG assays							
DRG IgG	91.9	54.5	97.1	100	100	9.5	14.6
Euroimmun IgG	95.9	72.7	100	100	100	13.5	22.9
Liaison IgG	93.2	54.5	100	100	100	4.1	14.6
NovaLisa IgG	95.9	81.8	97.1	100	100	10.8	22.9
Serion IgG	86.5	63.6	82.9	100	100	8.1	16.7
VirClia IgG	95.9	72.7	100	100	100	13.5	14.6
Overall Ig results (proportion of solitary IgM results)							
DRG[b]	91.9 (0.0)	54.5 (0.0)	97.1 (0.0)	100 (0.0)	100 (0.0)	20.3 (10.8)	50.0 (35.4)
Euroimmun[b]	95.9 (0.0)	72.7 (0.0)	100 (0.0)	100 (0.0)	100 (0.0)	18.9 (5.4)	50.0 (27.1)
Liaison[b]	95.9 (2.7)	72.7 (18.2)	100 (0.0)	100 (0.0)	100 (0.0)	12.2 (8.1)	43.8 (29.2)
NovaLisa[b]	97.3 (1.4)	90.9 (9.1)	97.1 (0.0)	100 (0.0)	100 (0.0)	29.7 (18.9)	58.3 (35.4)
Serion[b]	95.9 (9.5)	72.7 (9.1)	100 (17.1)	100 (0.0)	100 (0.0)	27.0 (18.9)	64.6 (47.9)
VirClia[b]	95.9 (0.0)	72.7 (0.0)	100 (0.0)	100 (0.0)	100 (0.0)	21.6 (8.1)	39.6 (25.0)
C6 IgM/IgG[c]	98.6	90.9	100	100	100	10.8	25.0
Euroimmun IgM/IgG[c]	97.3	81.8	100	100	100	8.1	22.9
Zeus IgM/IgG[c]	94.6	63.6	100	100	100	9.5	29.2

Yalancı pozitiflik
Sağlıklı grup: %8.1-29.7
Çapraz reaksiyon olası grup: %22.9-64.6

pathogens

MDPI

Article

Cross-Reactive Results in Serological Tests for Borreliosis in Patients with Active Viral Infections

Iwona Wojciechowska-Koszko [1,*], Paweł Kwiatkowski [1], Monika Sienkiewicz [2], Mateusz Kowalczyk [3], Edward Kowalczyk [4] and Barbara Dołęgowska [5]

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Abstract: Currently, serological tests for Lyme disease (LD), routinely performed in laboratories following the European Concerted Action on Lyme Borreliosis recommendations as part of two-stage diagnostics, are often difficult to interpret. This concerns both the generation of false positive and negative results, which frequently delay the correct diagnosis and implementation of appropriate treatment. The above problems result from both morphological and antigenic variability characteristics for the life strategy of the spirochete *Borrelia burgdorferi* sensu lato, a complicated immune response, and imperfections in diagnostic methods. The study aimed to check the reactivity of sera from 69 patients with confirmed infection with Epstein–Barr virus (EBV), cytomegalovirus (CMV) and BK virus (BKV) with *Borrelia* antigens used in serological tests: indirect immunofluorescence (IIFT), enzyme-linked immunosorbent (ELISA) and immunoblot (IB). In the group of patients infected with EBV, the highest percentage of positive/borderline anti-*Borrelia* IgM and IgG results was obtained in the following tests: IIFT (51.9% for IgM, 63.0% for IgG), ELISA (22.2% for IgM, 29.6% for IgG) and IB (11.1% for IgM, 7.4% for IgG). In the group of CMV-infected patients, the highest percentage of positive/borderline anti-*Borrelia* IgM results were obtained in the following tests: IB (23.1%), IIFT

check for updates

Citation: Wojciechowska-Koszko, I.; Kwiatkowski, P.; Sienkiewicz, M.; Kowalczyk, M.; Kowalczyk, E.; Dołęgowska, B. Cross-Reactive Results in Serological Tests for Borreliosis in Patients with Active Viral Infections. *Pathogens* 2022, *11*, 203. https://doi.org/10.3390/pathogens11020203

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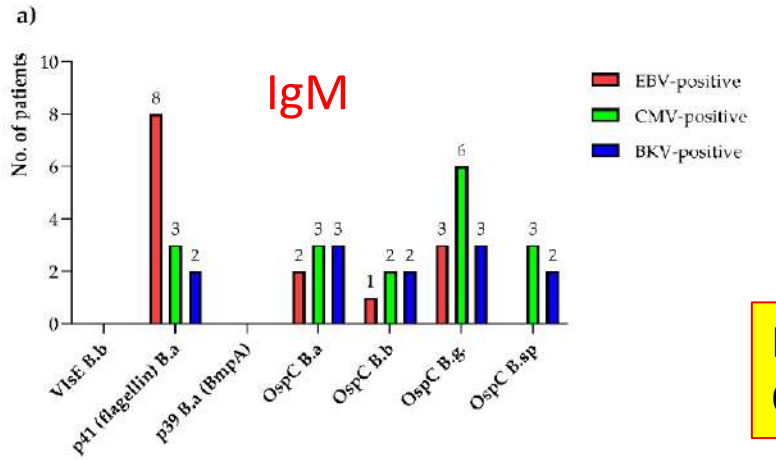
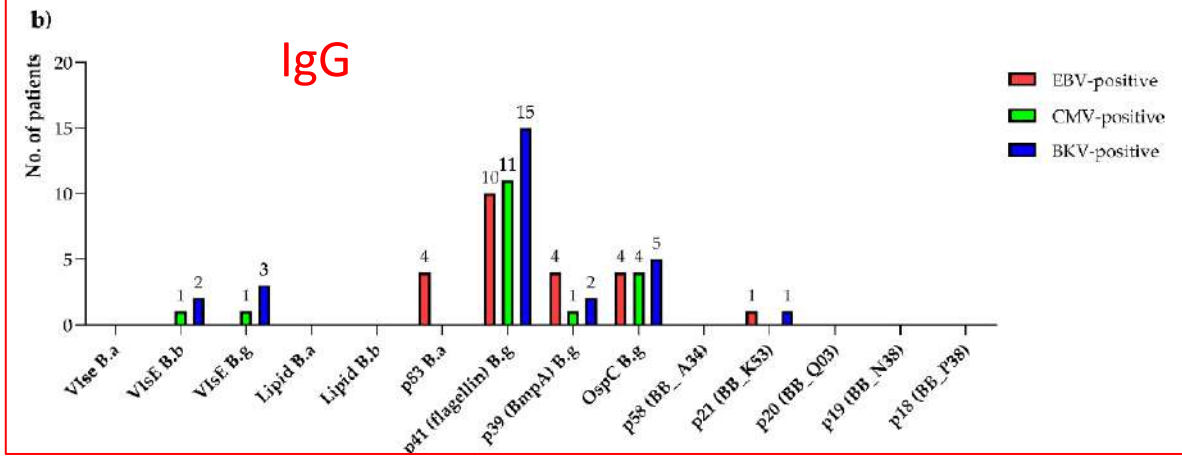


Flagellin ag (p41)
OspC



Borrelia afzelii, Borrelia burgdorferi, Borrelia garinii, Borrelia spielmanii.

European Journal of Clinical Microbiology & Infectious Diseases (2021) 40:1003–1012
https://doi.org/10.1007/s10096-020-04129-7

ORIGINAL ARTICLE

Lyme neuroborreliosis in Swedish children—PCR as a complementary diagnostic method for detection of *Borrelia burgdorferi* sensu lato in cerebrospinal fluid

Barbro H. Skogman[1,2] · Peter Wilhelmsson[3,4] · Stephanie Atallah[5] · Ann-Cathrine Petersson[6] · Katarina Ornstein[7] · Per-Eric Lindgren[3,8]

Received: 16 October 2020 / Accepted: 13 December 2020 / Published online: 2 January 2021

Abstract

The aim of this study was to evaluate polymerase chain reaction (PCR) as a diagnostic method for the detection of *Borrelia burgdorferi* s.l. in CSF of Swedish children with LNB. This study was performed retrospectively on CSF and serum samples collected from children evaluated for LNB ($n = 233$) and controls with other specific neurological disorders ($n = 59$) in a Swedish Lyme endemic area. For anti-*Borrelia* antibody index, the IDEIA Lyme Neuroborreliosis kit (Oxoid) was used. Two in-house real-time PCR assays targeting the *16S* rRNA gene were evaluated (TaqMan® and LUX™). Among patients classified as LNB cases ($n = 102$), five children (5%) were *Borrelia* PCR-positive in CSF with the TaqMan® assay. In the Non-LNB group ($n = 131$), one patient was *Borrelia* PCR positive with the TaqMan® assay. Among controls ($n = 59$), all CSF samples were PCR negative. When amplifying and sequencing *ospA*, we found *B. garinii* ($n = 2$), *B. afzelii* ($n = 2$), *B. bavariensis* ($n = 1$), and one untypable ($n = 1$). With the LUX™ technology, all CSF samples were PCR negative. The TaqMan® assay could detect only few cases ($n = 6$) of *B. burgdorferi* s.l. in CSF among children with LNB and the sensitivity was very low (5%). However, using larger CSF volumes and centrifugation of samples, the PCR technique could still be useful as a complementary diagnostic method when evaluating LNB. Furthermore, detection of spirochete DNA in clinical matrices, including CSF, is the method of choice for studying epidemiological aspects of LNB, a tick-borne emerging disease.

102 nöroboreliyoz tanılı çocuk

- 2 farklı 16sRNA hedefli PCR
- %5 PCR (+)
  - 2 *B.garinii*
  - 2 *B. bavariensis*
  - 1 tiplendirilemeyen
- 59 kontrol olgusunda PCR negatif

- Duyarlılığı arttırmak: BOS volümünün arttırılması ve santrifüjleme

THSK - Güncel analizler listesi

Yüksek Riskli Patojenler L.		140.313	*Borrelia burgdorferi* (Lyme) PCR ***(Doku materyalleri formalin ve parafin içermeyen SF içinde dıştan vidalı steril tüp/kapta gönderilmelidir.)***	Konvansiyonel PCR	1-2 mL BOS, 1-2 mL Eklem Sıvısı, 0.5 g Deri biyopsi örneği (Kandan önce biopsi örneği tercih edilir.)
Yüksek Riskli Patojenler L.	32.051	908.339	*Borrelia burgdorferi* (Lyme) PCR ***(Doku materyalleri formalin ve parafin içermeyen SF içinde dıştan vidalı steril tüp/kapta gönderilmelidir.)***	Real Time PCR	1-2 mL BOS, 1-2 mL Eklem Sıvısı, 0.5 g Deri biyopsi örneği
Yüksek Riskli Patojenler L.	30384-1	907.040	*Borrelia burgdorferi* antikor (Lyme) IgG	Western Blot	1-2 mL Serum
Yüksek Riskli Patojenler L.	30384	907.040	*Borrelia burgdorferi* antikor (Lyme) IgM	Western Blot	1-2 mL Serum
Yüksek Riskli Patojenler L.	32.048	907.050	*Borrelia burgdorferi* IgG	ELISA	1-2 mL Serum
Yüksek Riskli Patojenler L.	32.050	907.060	*Borrelia burgdorferi* IgM	ELISA	1-2 mL Serum
Yüksek Riskli Patojenler L.		140.812	*Borrelia burgdorferi* (Lyme) IgG *Avidite*	Line Immunoassay (LIA)	1-2 mL Serum
Yüksek Riskli Patojenler L.		140.813	*Borrelia burgdorferi* (Lyme) IgM	Line Immunoassay (LIA)	1-2 mL Serum

INFECTIOUS DISEASES, 2016
VOL. 48, NO. 6, 411–419
http://dx.doi.org/10.3109/23744235.2016.1144931

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ORIGINAL ARTICLE

Validate or falsify: Lessons learned from a microscopy method claimed to be useful for detecting *Borrelia* and *Babesia* organisms in human blood

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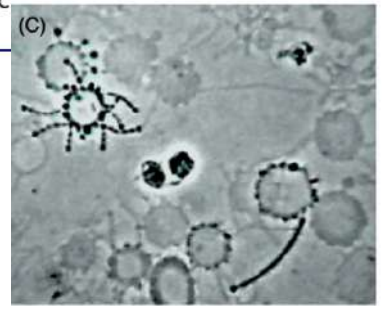
ABSTRACT

Background A modified microscopy protocol (the LM-method) was used to demonstrate what was interpreted as *Borrelia* spirochetes and later also *Babesia* sp., in peripheral blood from patients. The method gained much publicity, but was not validated prior to publication, which became the purpose of this study using appropriate scientific methodology, including a control group. **Methods** Blood from 21 patients previously interpreted as positive for *Borrelia* and/or *Babesia* infection by the LM-method and 41 healthy controls without known history of tick bite were collected, blinded and analysed for these pathogens by microscopy in two laboratories by the LM-method and conventional method, respectively, by PCR methods in five laboratories and by serology in one laboratory. **Results** Microscopy by the LM-method identified structures claimed to be *Borrelia*- and/or *Babesia* in 66% of the blood samples of the patient group and in 85% in the healthy control group. Microscopy by the conventional method for *Babesia* only did not identify *Babesia* in any samples. PCR analysis detected *Borrelia* DNA in one sample of the patient group and in eight samples of the control group; whereas *Babesia* DNA was not detected in any of the blood samples using molecular methods. **Conclusions** The structures interpreted as *Borrelia* and *Babesia* by the LM-method could not be verified by PCR. The method was, thus, falsified. This study underlines the importance of doing proper test validation before new or modified assays are introduced.

ARTICLE HISTORY
Received 7 August 2015
Revised 5 January 2016
Accepted 18 January 2016
Published online 15 February 2016

KEYWORDS
Lyme disease; Lyme borreliosis; babesiosis; Borrelia burgdorferi sensu lato; Babesia spp.; microscopy; PCR



Mikroskopi
- Hasta %66
- Kontrol %85

PCR
- Hasta – 1 olgu
- Kontrol – 8 olgu

Seroloji
- Hasta
  - 3 - IgG (+), PCR (-)
- Kontrol
  - 1 – IgG (+), PCR (-)

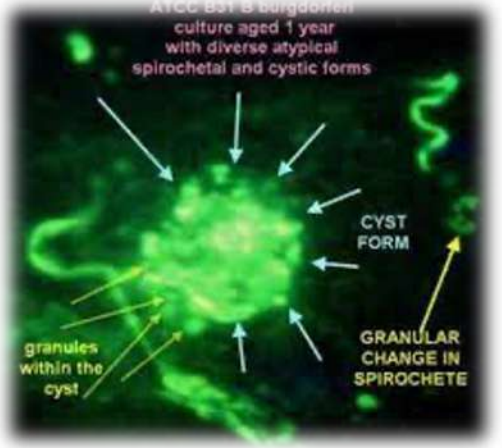
21 şüpheli hasta ve 41 sağlıklı kontrol
- Mikroskopi (LM yöntemi) (2 lab)
- PCR (5 ayrı lab – farklı protokoller)
- Seroloji (1 lab)

Mikroskopi sonuçları
- Hasta ve kontrolleri ayırd edememiş
- Sonuçlar diğer yöntemler ile doğrulanmamıştır.

PCR → laboratuvarlar arası fark var
- Kontaminasyon veya yalancı (+)
- Kalite kontrol çalışmalarına ihtiyaç var

CDC – Önerilmeyen testler

- İmmunfloresan boyama veya kistik (hücre duvarı defektli) *B.burgdorferi* formlarını saptama testleri
- İdrarda antijen testleri
- Lenfosit transformasyon testleri
- Kantitatif CD57 lenfosit testi
- Ters western blot testi
- İlk test (EIA) kullanılmadan yapılan IgM veya IgG blot testleri



Laboratory tests and practices that are not currently recommended

Print

CDC recommends using diagnostic tests for Lyme disease that have been cleared or approved by the U.S. Food and Drug Administration (FDA). Use of an FDA cleared or approved test provides assurance that the test has undergone adequate analytical and clinical validation and is safe and effective.

Some laboratories offer their own laboratory developed tests for Lyme disease whose clinical validity and safety have not been cleared or approved by the FDA. This means that information is lacking about the accuracy with which these tests identify, measure, or predict the presence or absence of Lyme disease in a patient. Examples include:

- Capture assays for antigens in urine
- Immunofluorescence staining, or cell sorting of cell wall-deficient or cystic forms of *Borrelia burgdorferi*
- Lymphocyte transformation tests
- Quantitative CD57 lymphocyte assays
- "Reverse Western blots"
- IgM or IgG blot assays without a previous enzyme immunoassay

Özet

- Test sonuçları her zaman enfeksiyon riski (öykü, klinik bulgular, endemisite, diğer inceleme sonuçları) ile birlikte yorumlanmalıdır.
- Laboratuvar tanı → sıklıkla antikorların saptanmasına dayalıdır.
  - Erken enfeksiyon döneminde antikorlar saptanamayabilir.
  - Antikorlar aylar – yıllar boyunca pozitif kalabilir.
    - Aktif enfeksiyon tanısında ve tedavi takibinde sorun !!
  - Hastanın şikayetleri 30 günden uzun süreli ise IgM testleri kullanılmamalıdır.
- Antikor testlerinde yalancı pozitiflikler saptanabilir.
  - Diğer kene ile bulaşan hastalıklar, bazı bakteriyal, viral enfeksyonlar, otoimmün hastalıklar

Gürbüz Doğan Ekşioğlu