Collaboration to Advance Pharmacy Enterprises

Collaboration to Optimize Medication Efficacy and Therapy

Community Pharmacy-Based Test to Treat Program for Lyme Disease

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FERRIS STATE UNIVERSITY
COLLEGE OF PHARMACY

Relevant Financial Relationship Disclosures

Michael Klepser declares that he has a relevant affiliation or financial arrangement as a member of the Advisory Board at Abbott Diagnostics.

Additionally, members of the District 4 Planning Committee and NABP staff involved in the planning of this activity do not have any current affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of NABP's CPE program within the last 24 months.

All relevant financial relationships have been mitigated.

AI Disclosure:

Use of AI: Gemini 3.5 Flash-Lite was used to create some images.

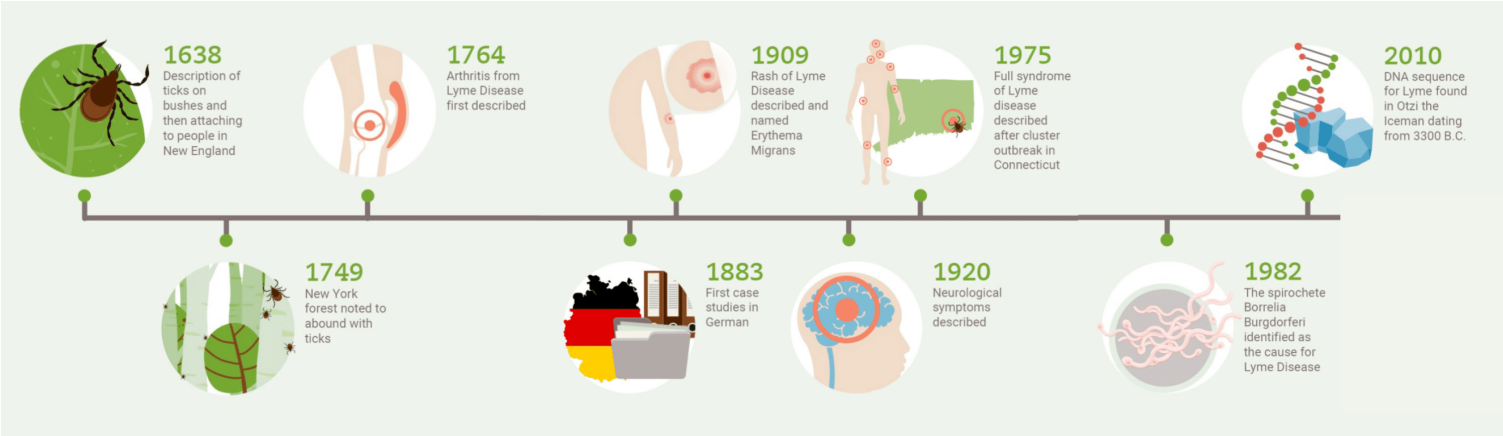
Objectives

After completing this activity, participants should be able to:

1. Describe the signs and symptoms associated with Lyme disease.
2. Explain how to make a diagnosis of Lyme disease.
3. Outline a care plan for a patient with Lyme disease.

History of Lyme Disease

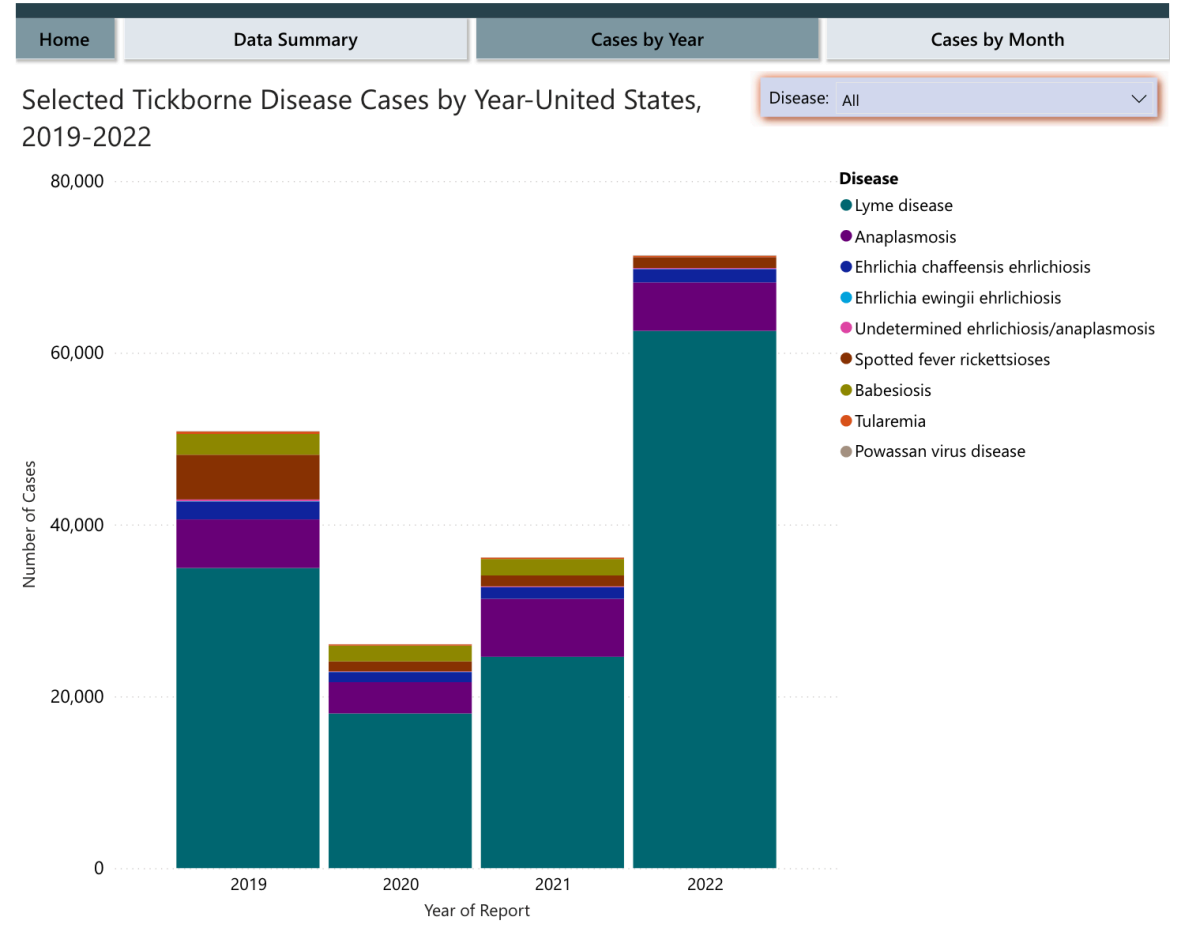
- The Lyme disease syndrome was not fully characterized and identified as a tick-borne disease until the 1970's.
  - Evidence of the disease has been found in 5,300-year-old mummy.
  - A German physician, Alfred Buchwald, first described the chronic skin rash, or erythema migrans, of what is now known to be Lyme disease more than 130 years ago.
  - The bacteria, *Borrelia burgdorferi*, was not identified until the 1980's.



https://richmondfunctionalmedicine.com/lyme-disease-history/

Tick-Borne Diseases

Disease	Average Annual Number of Reported Cases
Lyme Disease	37,000
Alpha-Gal Syndrome (AGS)	11,000
Spotted Fever Rickettsioses	5,317
Anaplasmosis and Ehrlichiosis	2,219
Babesiosis	2,214



https://www.cdc.gov/ticks/data-research/facts-stats/tickborne-disease-surveillance-data-summary.html

Tick-Borne Diseases

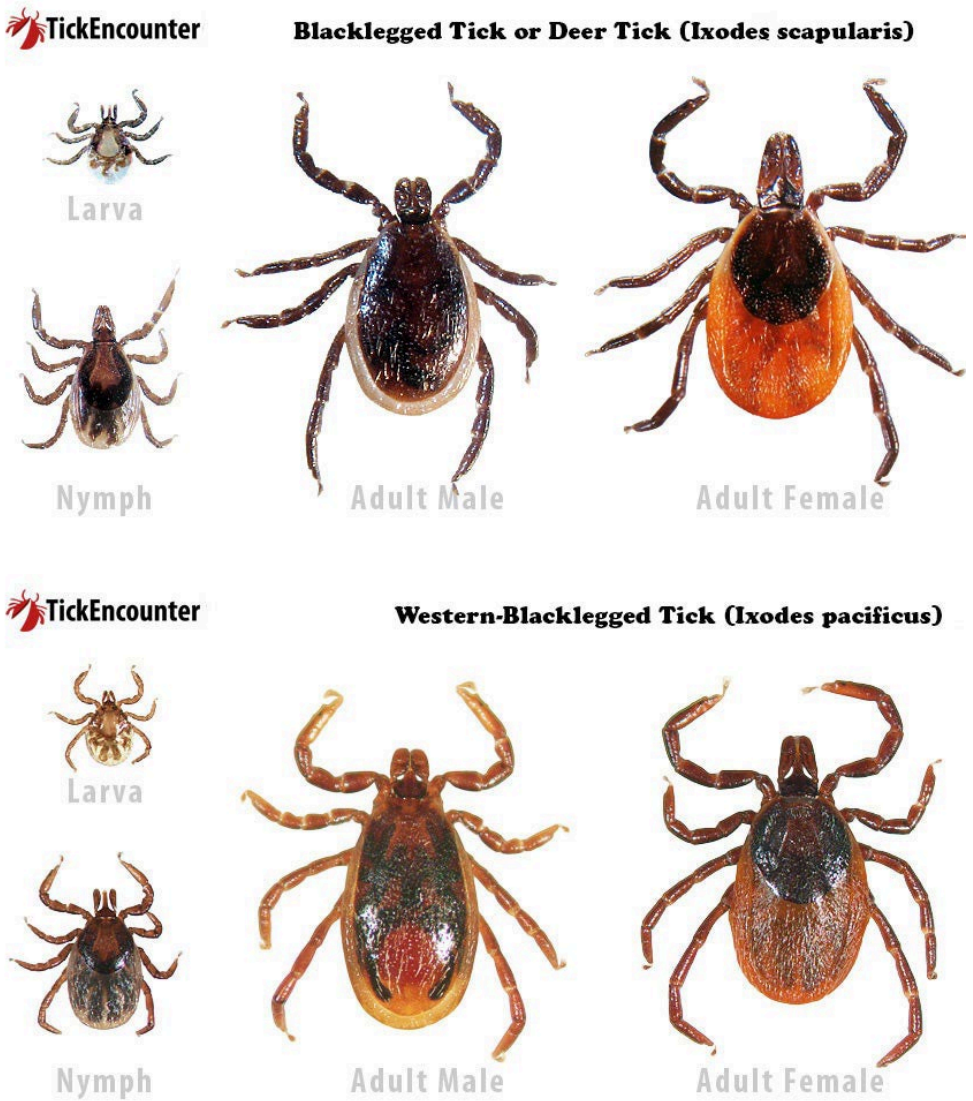
- Various tick species carry different pathogens and therefore are associated with different diseases.
  - Diseases are present where specific ticks are present.
  - Ticks migrate, so do diseases.

TICK GENUS	COMMON NAME	ASSOCIATED ILLNESS	PATHOGEN
Ixodes 	Blacklegged tick Deer tick Pacific tick	Lyme disease	*Borrelia burgdoferi* & *Borrelia mayonii*
		Relapsing fever	*Borrelia miyamotoi*
		Powassan encephalitis	Powassan virus
		Babesiosis	*Babesia microti*
		Human granulocytic anaplasmosis (HGA)	*Anaplasma phagocytophila*
		Cat scratch fever	*Bartonella henselae**
		Tick-borne encephalitis	Tick-borne encephalitis virus
*Amblyomma*** 	Lone Star tick	Human monocytic ehrlichiosis (HME)	*Ehrlichia spp.*
		Southern tick-associated rash illness (STARI)	unknown
		Heartland virus disease	Heartland virus
		Bourbon virus disease	Bourbon virus
		Tularemia	*Francisella tularensis*
Dermacentor 	Dog tick Rocky Mountain Wood tick	Spotted fever rickettsiosis***	*Rickettsia spp.*
		Tularemia	*Francisella tularensis*

https://www.globallymealliance.org/tick-table/

Lyme Disease

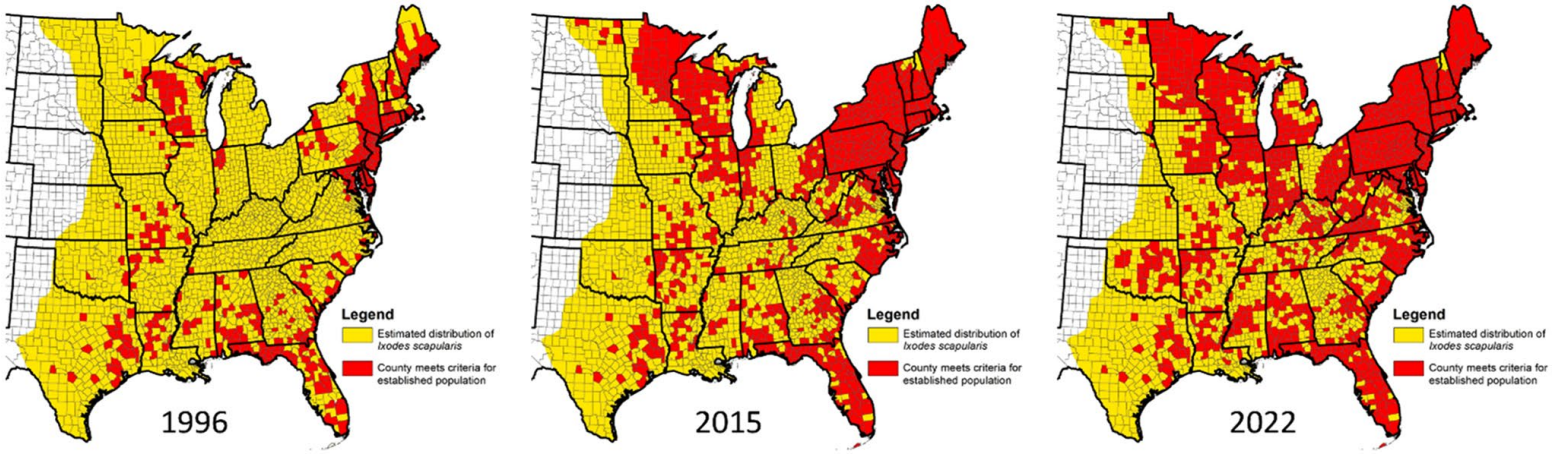
- Lyme disease is caused by the bacterium *Borrelia burgdorferi.*
  - Blacklegged tick/Deer tick (*Ixodes scapularis*)
  - Western blacklegged tick (*Ixodes pacificus*)

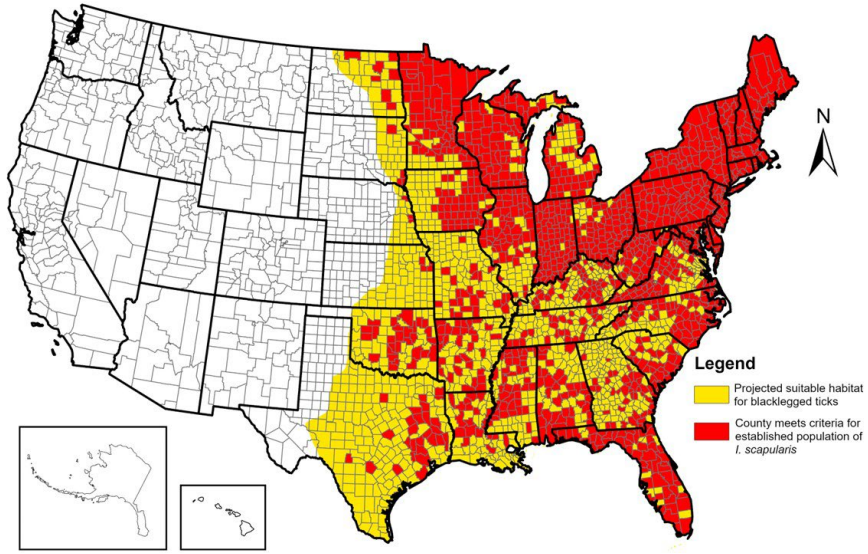


https://web.uri.edu/tickencounter/species/western-blacklegged-tick/

Migration of Ixodes scapularis

- An established county means six or more blacklegged ticks of a single life stage or more than one life stage of blacklegged tick was collected in a county within a 12-month period.
- A county that is not labeled as established does not mean ticks are absent.
- Once a tick species is recorded as established within a county, the status will remain “established” in subsequent years.



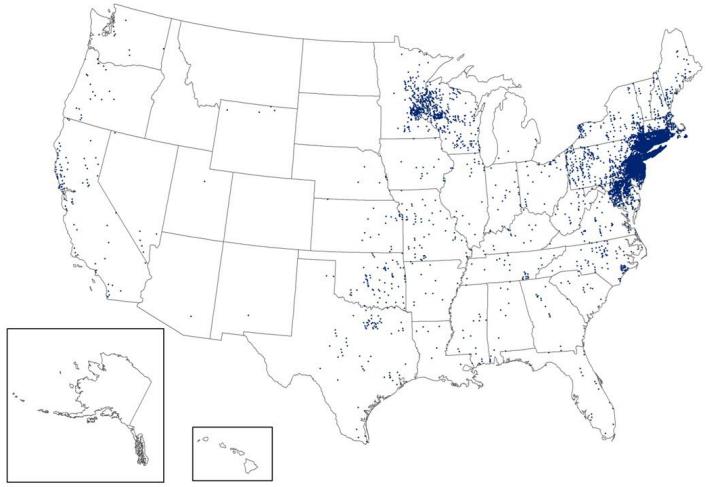


2025

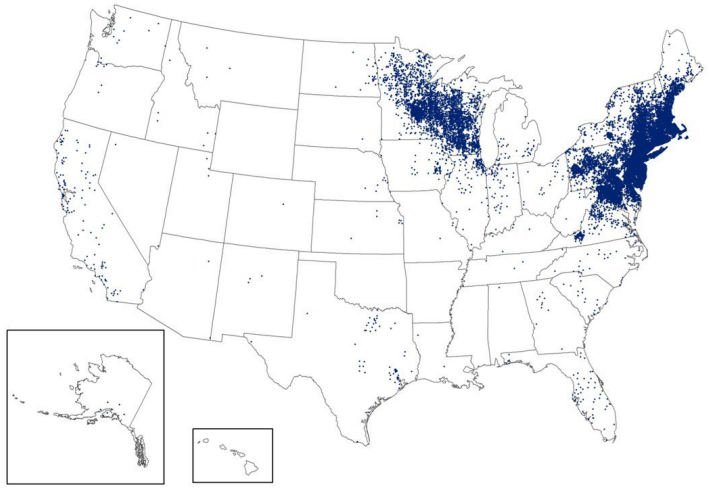
https://www.cdc.gov/ticks/data-research/facts-stats/blacklegged-tick-surveillance.html

Spread of Lyme Disease

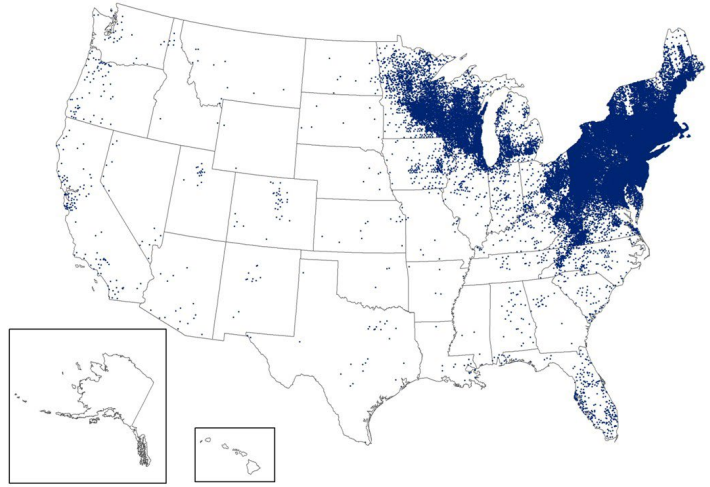
Reported Cases of Lyme Disease



1995



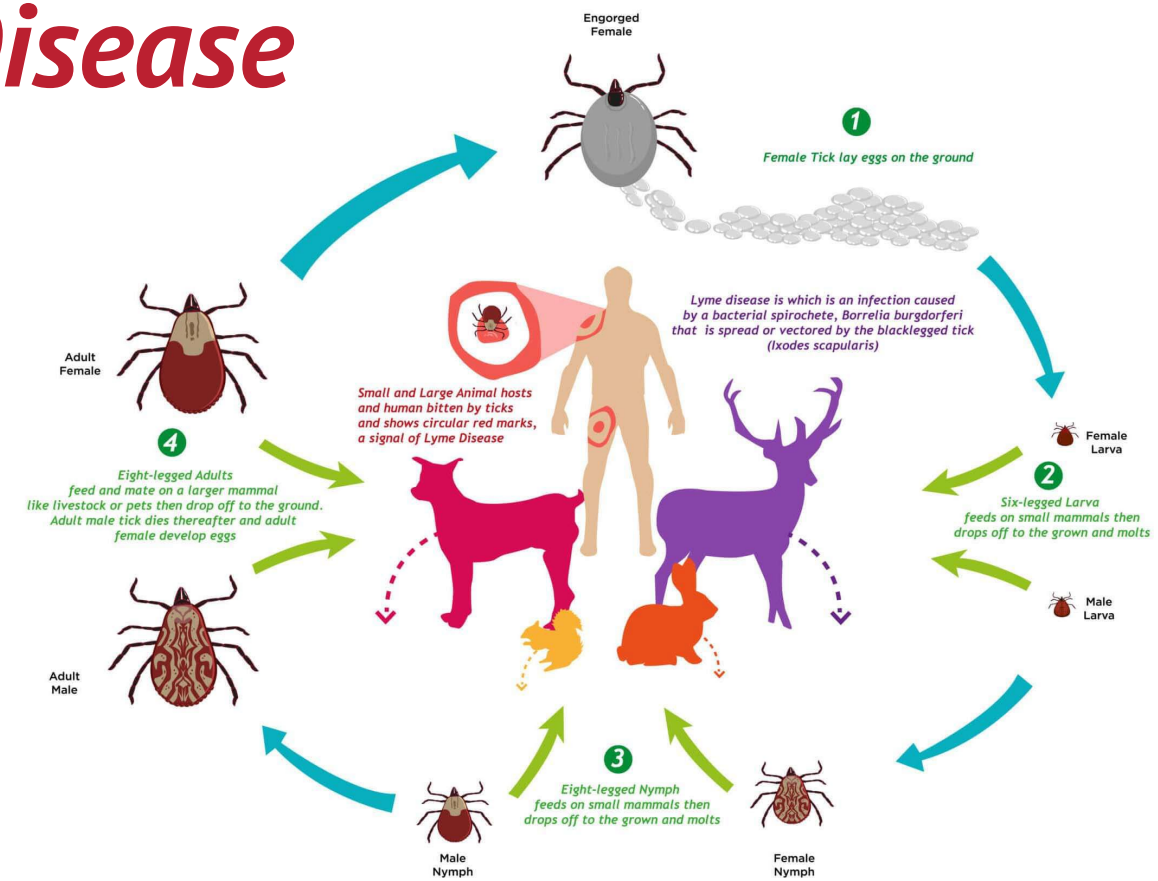
2010



2023

https://www.cdc.gov/lyme/data-research/facts-stats/lyme-disease-case-map.html

Lifecycle of Ixodes scapularis and Transmission Lyme Disease

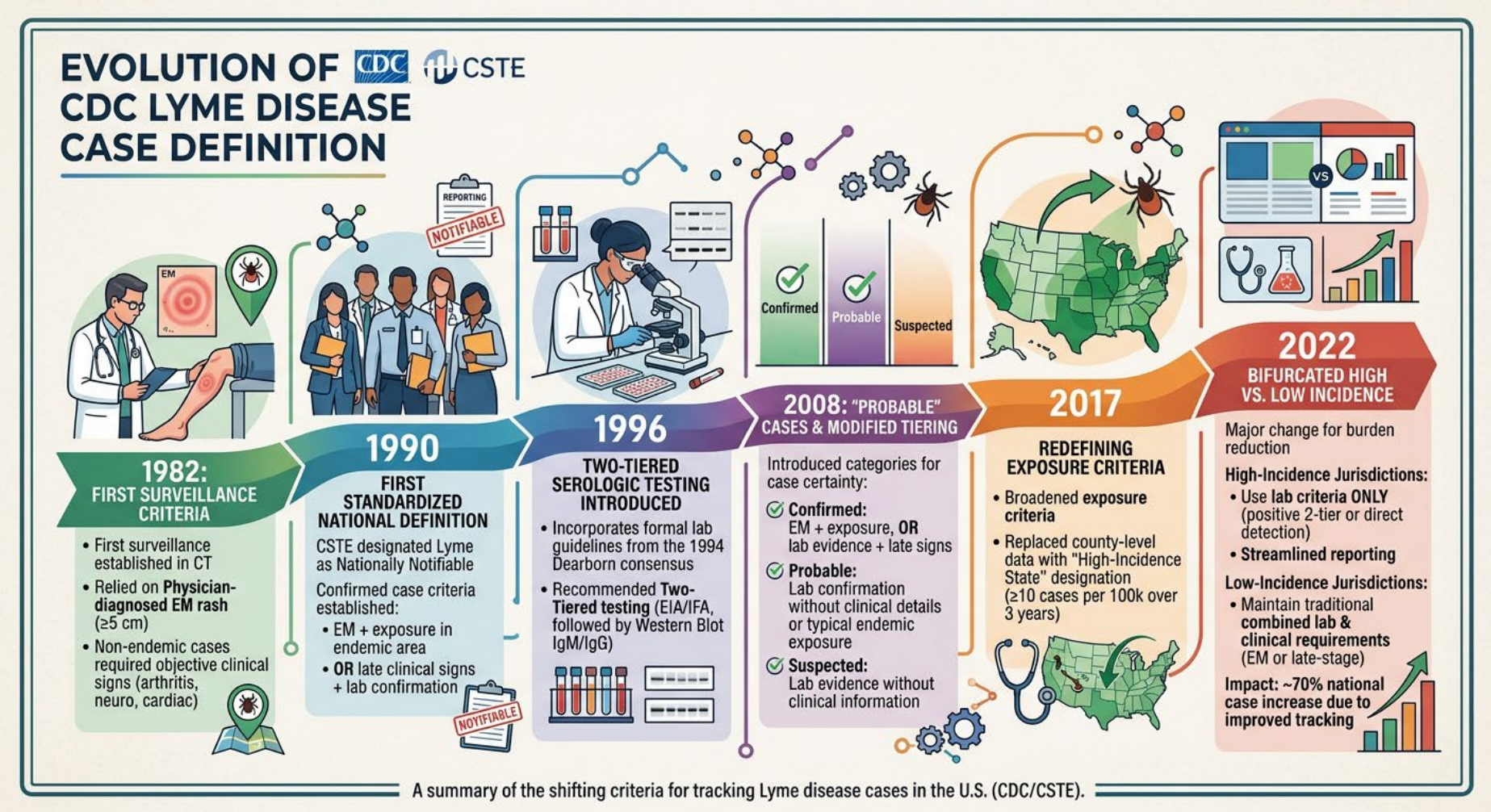


- In the summer of year one, eggs deposited in late spring hatch into six-legged **larvae,** which feed once on a variety of small mammals or birds. Engorged larvae drop from the host to the ground where they overwinter and molt.
- Larvae do not carry tick-borne pathogens but may pick up pathogens during their first blood meal from a diseased host and subsequently transmit such pathogens during their second and third feedings as nymphs or adults.

- In year two, nymphal stage blacklegged ticks will begin to feed and peak activity is typically from **May through July**. At this time, the nymph may transmit disease-causing organisms to humans or to wild or domestic mammals. Both larvae and nymphs have the potential to become infected with Lyme disease bacteria (*B. burgdorferi*) and other tick-borne pathogens such as *Babesia microti*–the organism that causes babesiosis and *Anaplasma phagocytophilum* – the organism that causes human granulocytic ehrlichiosis.

https://wisconsin-ticks.russell.wisc.edu/ixodes-scapularis-life-cycle/
https://jcvcd.gov/ticks/tick-life-cycle/

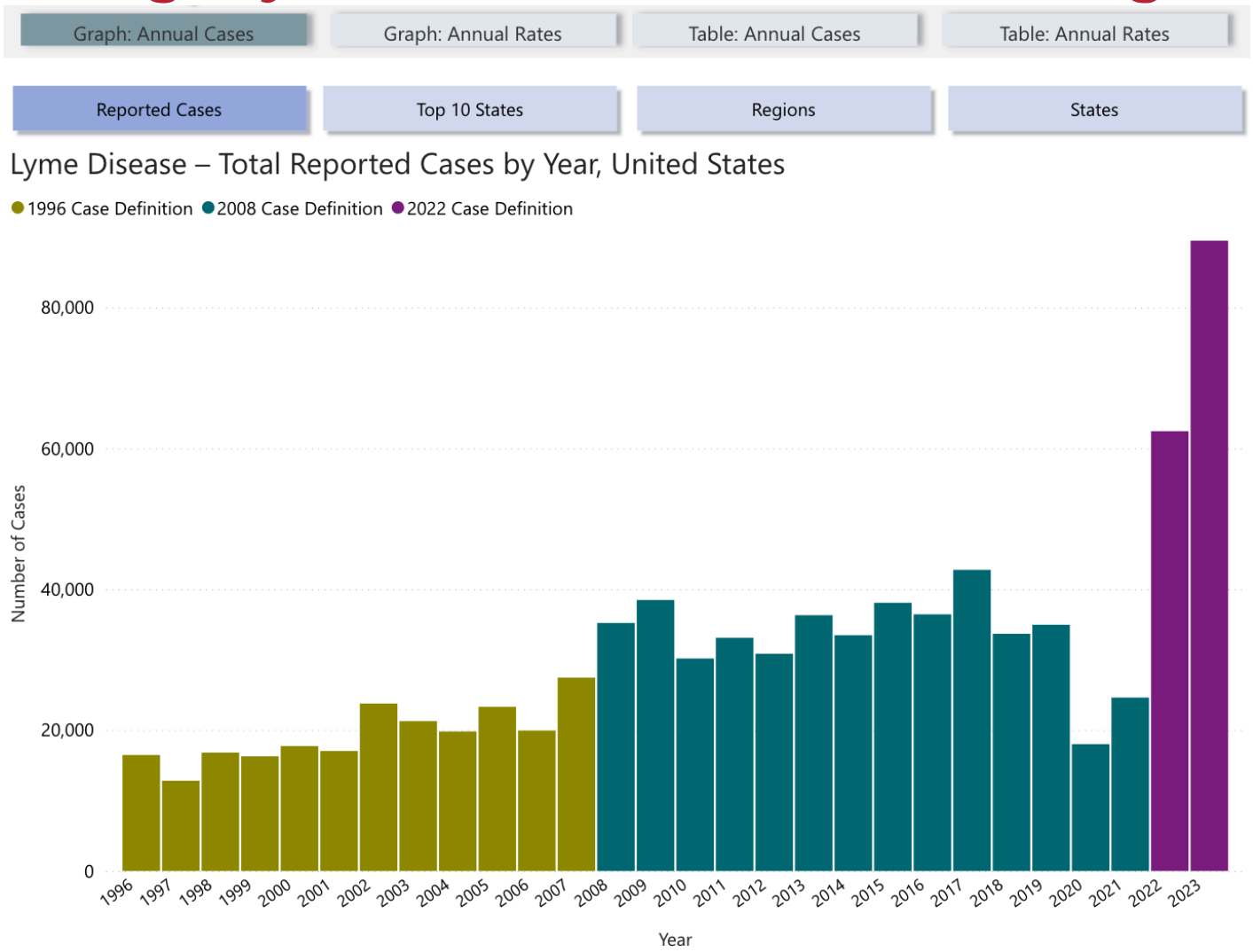
Evolution of Lyme Disease Case Definitions



https://ndc.services.cdc.gov/case-definitions/lyme-disease-1995/

Image created with Gemini

Evolution of Lyme Disease Case Definitions



https://www.cdc.gov/lyme/data-research/facts-stats/surveillance-data-1.html

Current Lyme Disease Case Definition

- Clinical criteria
  - One of the following early or late-stage manifestations
    - Erythema migrans (EM)
    - Recurrent, brief attacks (weeks or months) of objective joint swelling in one or a few joints.
    - Nervous system (lymphocytic meningitis; cranial neuritis, particularly facial palsy (unilateral or bilateral); radiculoneuropathy; or, rarely, encephalomyelitis)
    - Cardiovascular system. Acute onset of high-grade (2nd-degree or 3rd-degree) atrioventricular conduction defects that resolve in days to weeks.

- Laboratory Criteria
  - Confirmed laboratory evidence
    - Isolation of *B. burgdorferi* or *B. mayonii* in culture.

      OR
    - Detection of *B. burgdorferi* or *B. mayonii* in a clinical specimen by group-specific nucleic acid amplification test (NAAT) assay.

      OR

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https://ndc.services.cdc.gov/case-definitions/lyme-disease-2022/

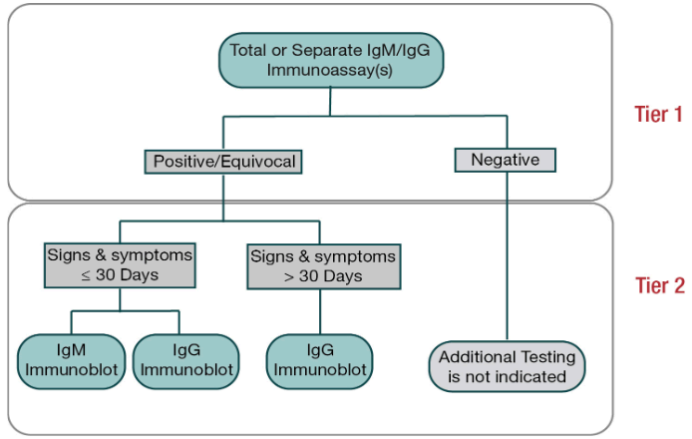
Confirmed Laboratory Evidence (Continued)

- Detection of *B. burgdorferi* group-specific antigens by immunohistochemical assay on biopsy or autopsy tissues,

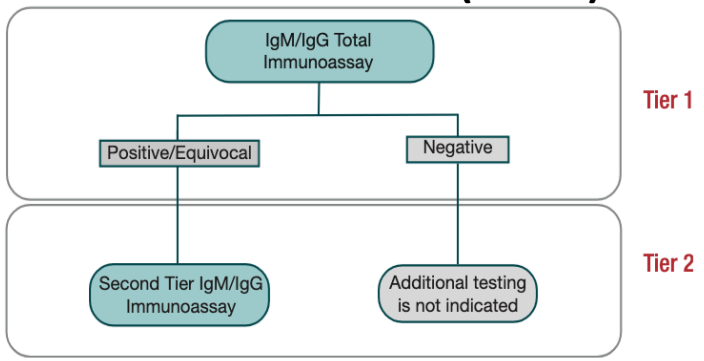
OR

- Positive serologic tests in a two-tier or equivalent format, including:
  - ***Standard two-tier test (STTT):*** a positive or equivocal first-tier screening assay, often an enzyme immunoassay [EIA] or immunofluorescence assay [IFA] for immunoglobulin M (IgM), immunoglobulin G (IgG), or a combination of immunoglobulins, **followed by** a concordant positive IgM or IgG immunoblot interpreted according to established criteria, **OR**
  - ***Modified two-tier test (MTTT):*** positive or equivocal first-tier screen, **followed by** a different, sequential positive or equivocal EIA in lieu of an immunoblot as a second-tier test.

Standard two-tier test (STTT):



Modified two-tier test (MTTT):



https://www.cdc.gov/lyme/media/pdfs/2024/05/Suggested-Reporting-Language-Interpretation-and-Guidance-Regarding-Lyme-Disease-Serologic-Test-Results.pdf
https://ndc.services.cdc.gov/case-definitions/lyme-disease-2022/

Signs and Symptoms of Lyme Disease

Early Stage (3 to 30 Days)	Early Disseminated Stage (3 to 10 Weeks)	Late Disseminated Stage (2 to 12 Months or Longer)
• **Erythema migrans rash:** • An expanding red ring that often resembles a bull's-eye, though it can also be uniformly red. It is usually warm but typically not painful or itchy. It appears in about 70% to 80% of cases. • **Flu-like symptoms:** Fever, chills, fatigue, headaches, and swollen lymph nodes. • **Aches:** Muscle and joint stiffness or pain.	• **Neurological issues:** Facial palsy (drooping on one or both sides of the face), severe headaches, and neck stiffness (signs of meningitis). • **Nerve pain:** Numbness, tingling, or shooting pains in the hands or feet. • **Heart problems:** Heart palpitations or an irregular heartbeat (Lyme carditis). • **Additional rashes.**	• If left untreated for months, severe complications can emerge: • **Lyme arthritis:** Severe joint pain and swelling, most commonly affecting large joints like the knees. • **Chronic nervous system changes:** Long-term memory complaints, difficulty concentrating, or nerve damage

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https://www.cdc.gov/lyme/signs-symptoms/index.html

Signs and Symptoms of Lyme Disease

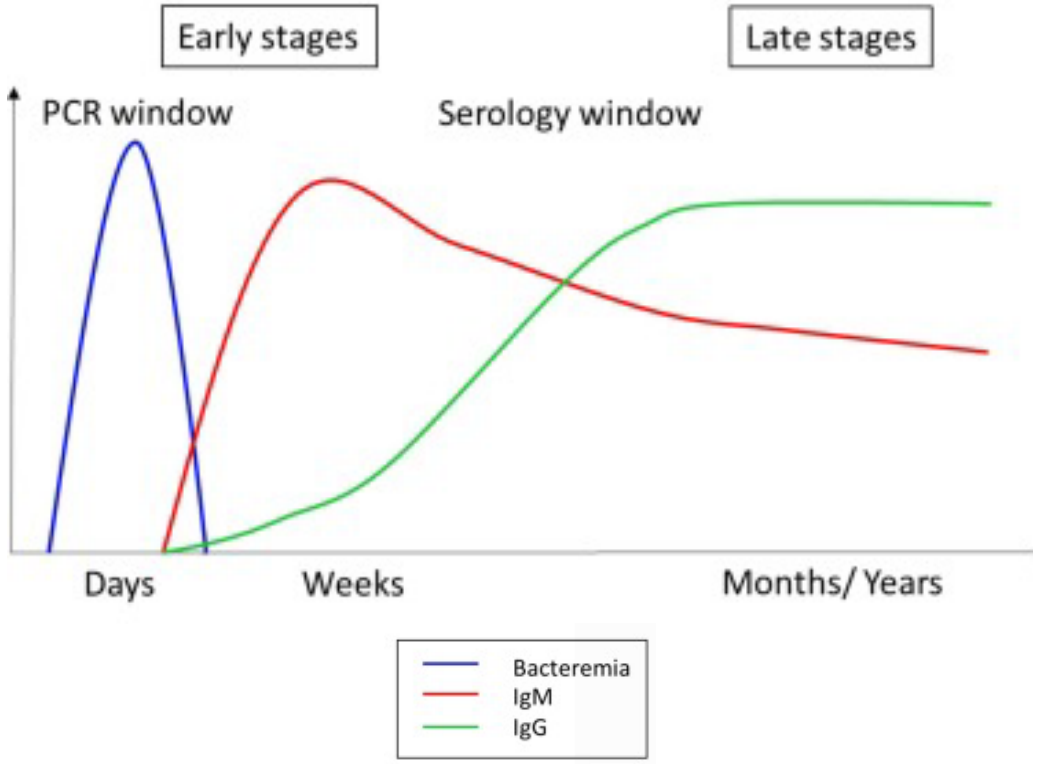
- Which of the rashes is/are erythema migrans?



https://aldf.com/pictures-of-erythema-migrans/

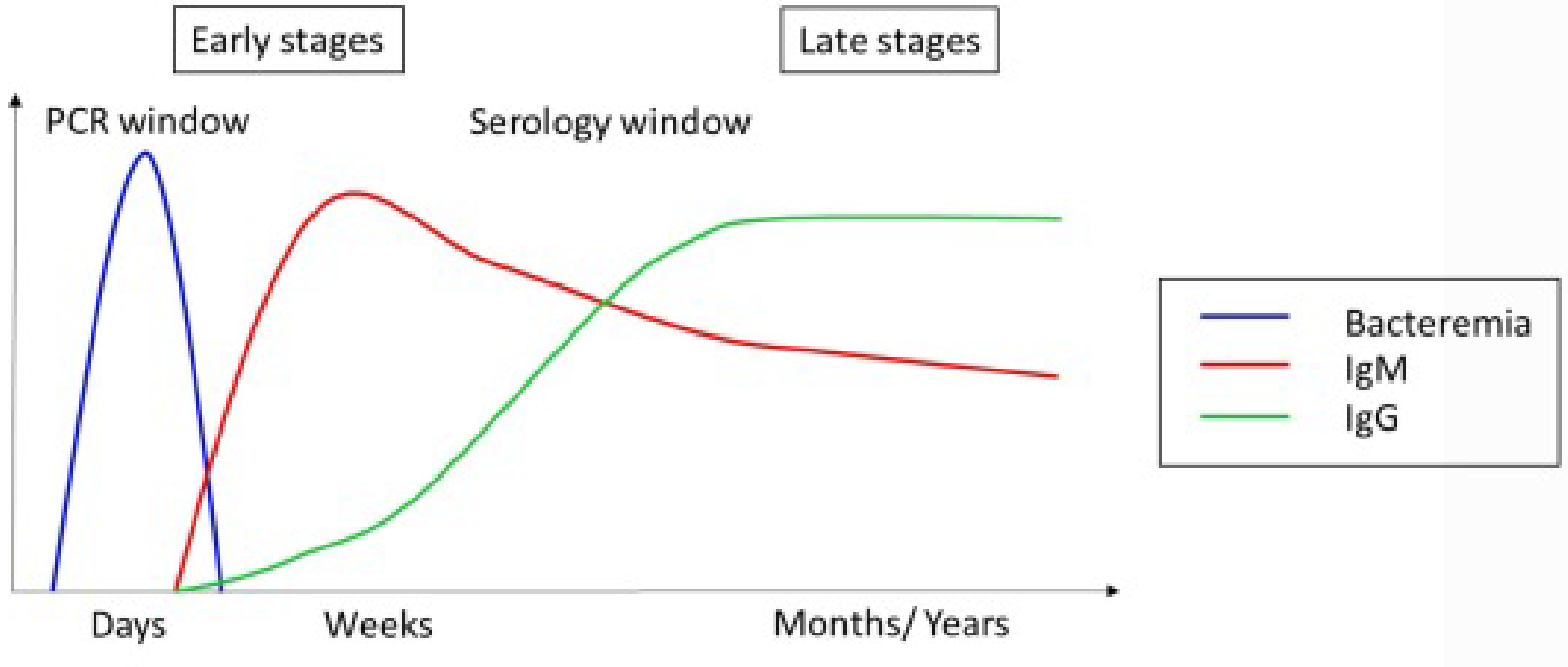
Diagnosing Lyme Disease

- Consider likelihood of exposure to *Ixodes scapularis.*
  - Local and travel
  - Timing of potential exposure
- Assess signs and symptoms
- Consider laboratory testing
  - Interpret results in light of timing of exposure



StacyM, et al. Clin Biochemistry.2023;117 ;4-9.

Lyme Disease Serology



StacyM, et al. Clin Biochemistry.2023;117 ;4-9.

CLIA-Waived POCT for Lyme Disease

- There is currently one CLAI-waived POCT for Lyme disease
  - Manufacturer: QuidelOrtho
  - Assay: Immunofluorescence for the rapid differential detection of human IgM and/or IgG antibodies to *Borrelia burgdorferi*
  - Patient population: Patients suspected of *B. burgdorferi* infection at least 2 weeks' ago.
  - Specimen: Finger-stick whole blood
  - Run time: 15 minutes
  - Analyzer cost: $1,500-$
  - Cost per test: $39/test



https://www.quidelortho.com/global/en/products/sofia-platform/sofia-2-lyme-fia1

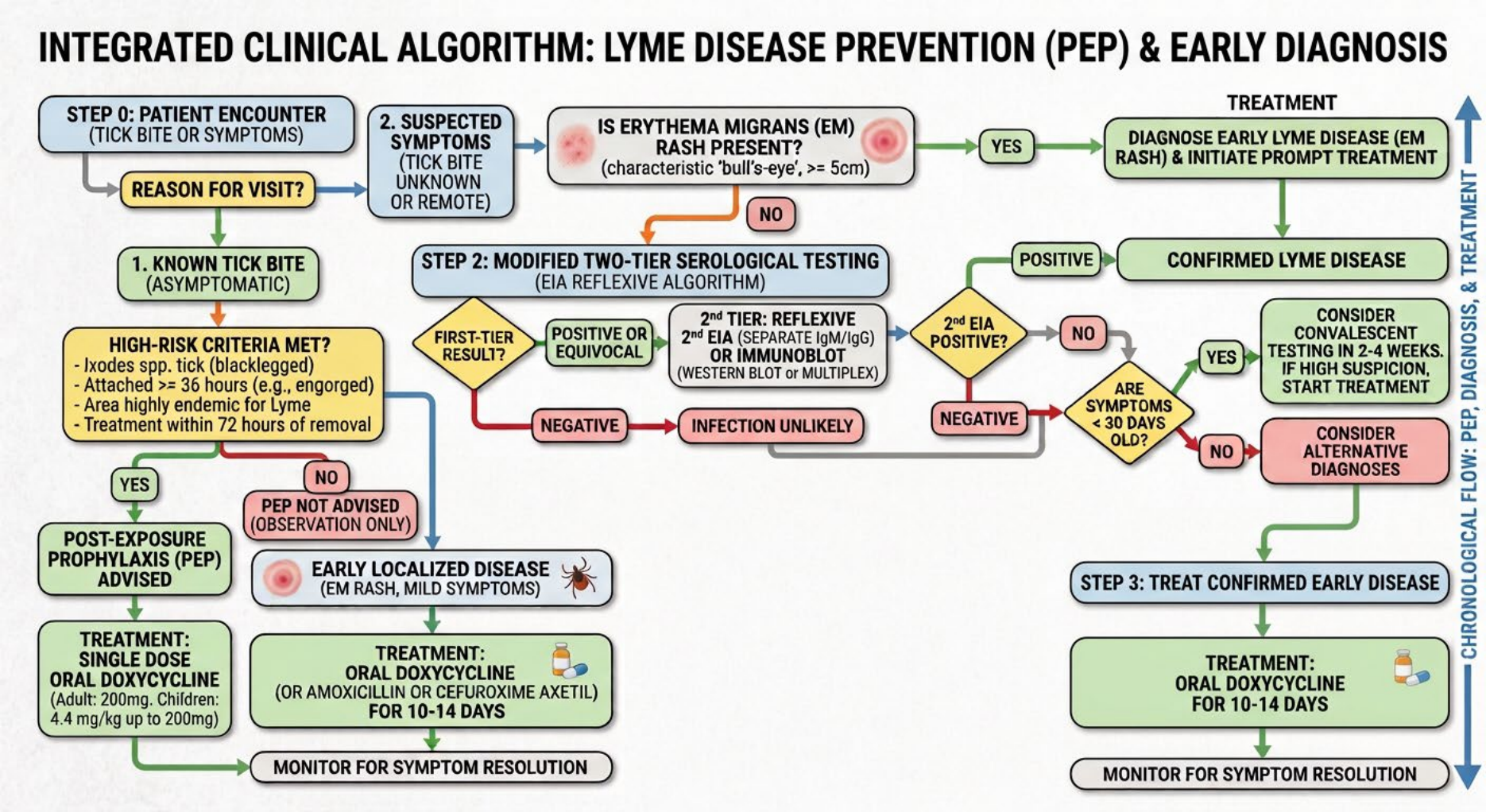
CLIA-Waived POCT for Lyme Disease Performance

Lyme IgG Results for Sofia Lyme FIA with Sofia Compared to Predicate Assay

		Sofia IgG				Predicate IgG			
Category	**n**	**Pos**	**Neg**	**% Sens**	**95%CI**	**Pos**	**Neg**	**% Sens**	**95%CI**
Acute, < 1 month, with EM	**64**	50	14	78.1%	66.5-86.6%	28	36	43.8%	32.3-55.9%
Acute, 1-2 months, with EM	**4**	4	0	100%	45.4-100.0%	3	1	75.0%	28.9-96.6%
Convalescent, 3-12 months, with EM	**15**	10	5	66.7%	41.5-85.0%	6	9	40.0%	19.8-64.3%
Late Lyme (>1 yr), Neuro or Arthritic	**12**	12	0	100%	71.8-100.0%	10	2	83.3%	54.0-96.5%
All Categories	**95**	76	19	80.0%	70.8-86.9%	47	48	49.5%	39.6-59.4%

https://www.quidelortho.com/global/en/products/sofia-platform/sofia-2-lyme-fia1

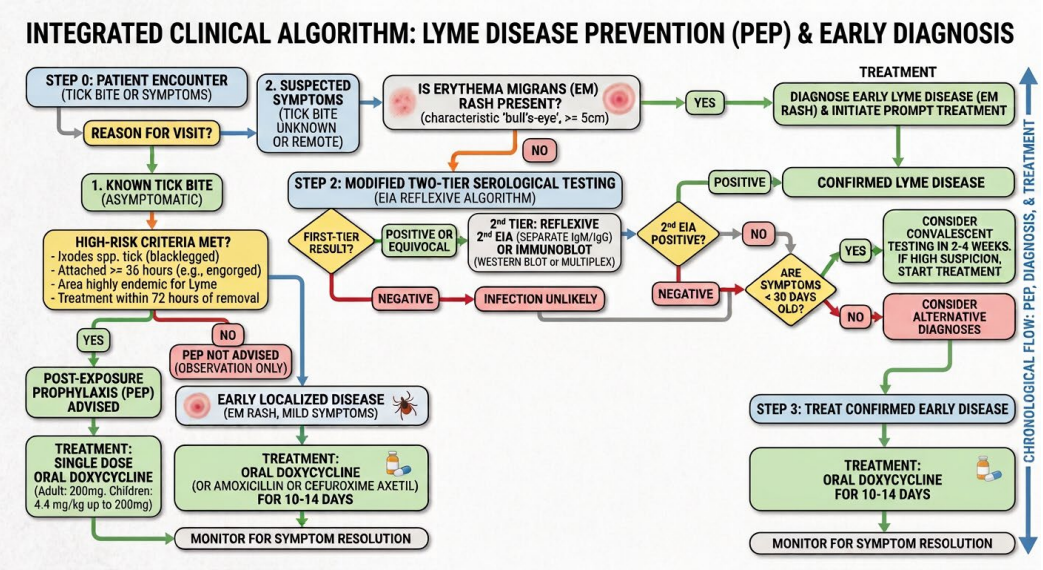
Lyme Disease Care Plan



https://www.cdc.gov/lyme/hcp/diagnosis-testing/index.html
https://www.cdc.gov/lyme/media/pdfs/2024/05/Suggested-Reporting-Language-Interpretation-and-Guidance-Regarding-Lyme-Disease-Serologic-Test-Results.pdf
https://www.cdc.gov/lyme/hcp/communication-resources/index.html
Image generated using Gemini

Translating Care to Community Pharmacy

- Evaluation, Tier 1 immunoassay, PEP, and treatment of high-risk individuals can be performed in a community pharmacy.
- Health department laboratories or commercial laboratories may be used for Tier 2 immunoblot testing.



https://www.cdc.gov/lyme/hcp/diagnosis-testing/index.html
https://www.cdc.gov/lyme/media/pdfs/2024/05/Suggested-Reporting-Language-Interpretation-and-Guidance-Regarding-Lyme-Disease-Serologic-Test-Results.pdf
https://www.cdc.gov/lyme/hcp/communication-resources/index.html
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Proposed Business Case

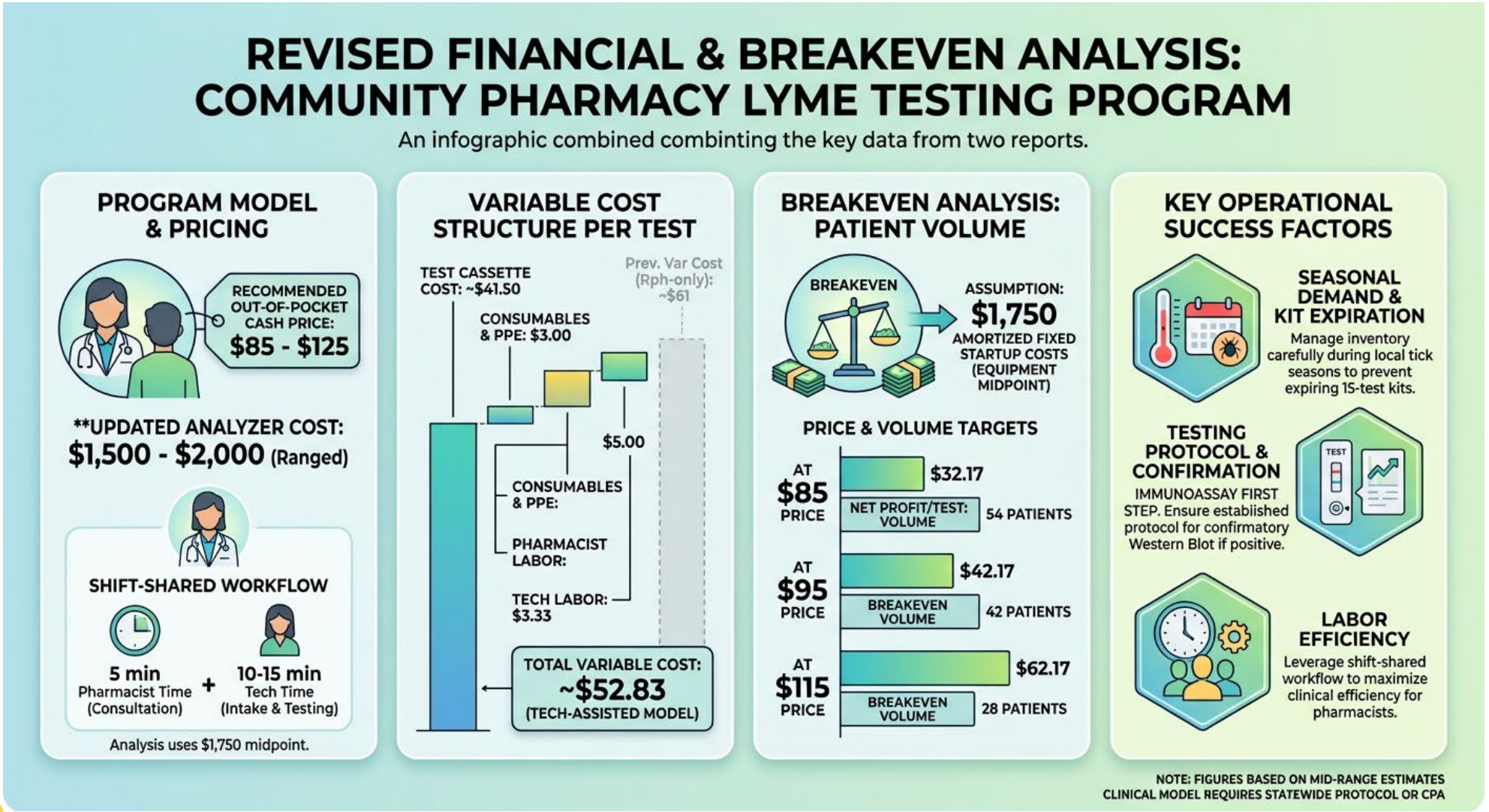


Image generated using Gemini

Pilot Program

- In spring 2027
  - Partnering with 1 chain and 3 independent pharmacies.
  - This will be rolled out as a cash for service program.
  - Contact me if you have interest in learning more about the pilot and possible participation.

Self-Assessment Questions

1. A patient was hiking last week (June) in the upper peninsula of Michigan. When she returns home, she develops a fever, aches, and a rash. What is the most appropriate course of action for this patient?
   A. Provide doxycycline as a single dose for post exposure prophylaxis.
   B. Wait for 7 days and then perform an immunoassay on the patient.
   C. Recommend treatment with doxycycline for 10-14 days.
   D. Perform an immunoassay test now. If the results are positive, treat with doxycycline. If the results are negative, monitor for symptom resolution but do not prescribe doxycycline.

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Self-Assessment Questions

1. Which of the following is an unlikely reason for why cases of Lyme disease have increased dramatically over the past decade.
   A. Modified case definition for Lyme disease.
   B. Approval of better tests for Lyme disease.
   C. Migration of Ixodes scapularis as climate change has occurred.
   D. Increased public awareness of Lyme disease.

Self-Assessment Questions

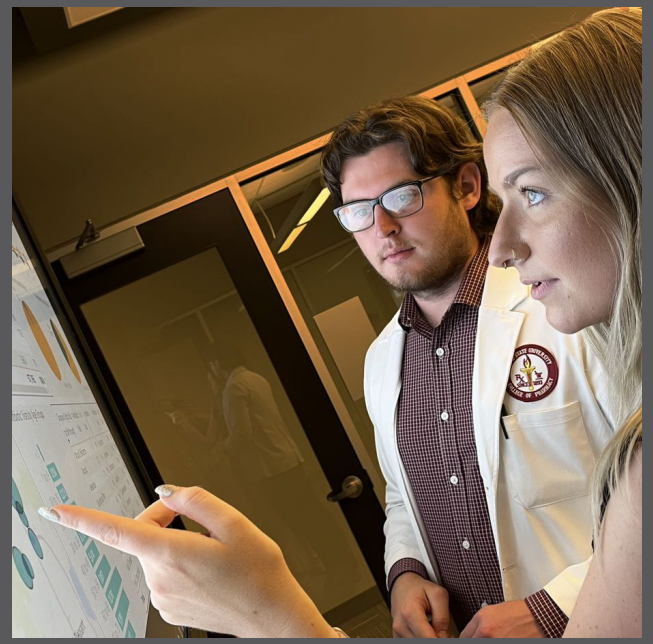
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Self-Assessment Questions

1. Which of the following is most likely to be observed in a patient with early-stage Lyme disease?
   A. Erythema migrans
   B. Heart block
   C. Facial palsy
   D. Pain and swelling of joints

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Collaboration to Optimize Medication Efficacy and Therapy (COMET)

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CAPE COMET

Session Code

LG73

0.5 contact hours (0.05 CEU)

0205-9999-26-110-L01-P

0205-9999-26-110-L01-T

Claims must be submitted by the morning of December 14, 2026.

https://nabp.pharmacy/claimcpe

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