

# ALL TEST™ Lyme IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)

## Package Insert

REF ILY-402 English

A rapid test for the qualitative detection of IgG and IgM antibodies to Borrelia in human whole blood, serum or plasma specimens.

For professional *in vitro* diagnostic use only.

### 【INTENDED USE】

The Lyme IgG/IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Borrelia in human whole blood, serum or plasma specimen.

### 【SUMMARY】

Lyme disease, also known as Lyme borreliosis, is an infectious disease caused by bacteria of the *Borrelia* sp. which is spread by ticks.<sup>2</sup> The most common sign of infection is an expanding area of redness on the skin, known as erythema migrans, that begins at the site of a tick bite about a week after it has occurred.<sup>1</sup> The rash is typically neither itchy nor painful. Approximately 25–50% of infected people do not develop a rash.<sup>1</sup> Other early symptoms may include fever, headache and feeling tired.<sup>1</sup> If untreated, symptoms may include loss of the ability to move one or both sides of the face, joint pains, severe headaches with neck stiffness, or heart palpitations, among others.<sup>1</sup> Months to years later, repeated episodes of joint pain and swelling may occur.<sup>1</sup> Occasionally, people develop shooting pains or tingling in their arms and legs.<sup>1</sup> Despite appropriate treatment, about 10 to 20% of people develop joint pains, memory problems, and feel tired for at least six months.<sup>1,4</sup>

Lyme disease is transmitted to humans by the bite of infected ticks of the genus Ixodes.<sup>5</sup> Usually, the tick must be attached for 36 to 48 hours before the bacteria can spread.<sup>6</sup> In North America, *Borrelia burgdorferi* and *Borrelia mayonii* are the causes.<sup>7,8</sup> In Europe and Asia, the bacteria *Borrelia alzelli* and *Borrelia garinii* are also causes of the disease.<sup>2</sup> The disease does not appear to be transmissible between people, by other animals, or through food.<sup>9</sup> Diagnosis is based upon a combination of symptoms, history of tick exposure, and possibly testing for specific antibodies in the blood.<sup>3,8</sup> Blood tests are often negative in the early stages of the disease.<sup>2</sup> Testing of individual ticks is not typically useful.<sup>9</sup>

### 【PRINCIPLE】

The Lyme IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to *Borrelia* in whole blood, serum or plasma specimens. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with *Borrelia* antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region, if the specimen contains IgG antibodies to *Borrelia*. A colored line will appear in IgG test line region as a result of this. Similarly, anti-human IgM is coated in IgM test line region and if specimen contains IgM antibodies to *Borrelia*, the conjugate-specimen complex reacts with anti-human IgM. A colored line will appear in IgM test line region as a result.

Therefore, if the specimen contains anti-*Borrelia* IgG antibodies, a colored line will appear in IgG test line region. If the specimen contains anti-*Borrelia* IgM antibodies, a colored line will appear in IgM test line region. If the specimen does not contain anti-*Borrelia* antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

### 【REAGENTS】

The test contains anti-human IgM and anti-human IgG as the capture reagent, *Borrelia* antigen as the detection reagent. A goat anti-human IgG is employed in the control line system.

### 【PRECAUTIONS】

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

### 【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### 【SPECIMEN COLLECTION AND PREPARATION】

- The Lyme IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **Fingerstick Whole Blood Specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
  - Touch the end of the capillary tube to the blood until filled to approximately 10µL. Avoid air bubbles.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, for long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
- EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

### 【MATERIALS】

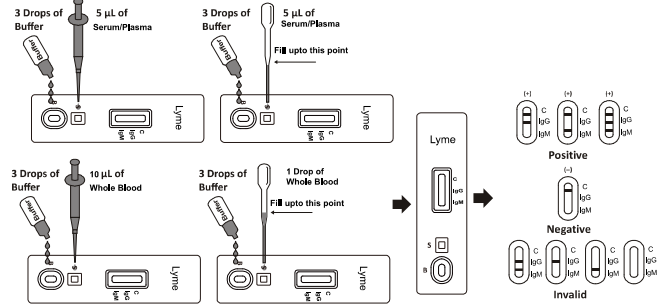
- Test Cassettes
- Materials provided
  - Droppers
  - Package Insert
  - Buffer
- Materials required but not provided
  - Centrifuge (for plasma only)
  - Timer
- Specimen Collection Containers
- Lancets (for fingerstick whole blood only)
- Pipette and Disposable Tips (optional)

### 【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
- Place the cassette on a clean and level surface.
  - For **Serum/Plasma** specimen:
    - Use a **pipette**: To transfer **5µL of Serum/Plasma** to the specimen well(S), then add **3drops of buffer (approximately 120µL) to the buffer well (B)**.
    - Use a **dropper**: Hold the dropper vertically, draw the specimen up to the **upper end of the nozzle** as shown in illustration below (**approximately 5µL**). Transfer the specimen to the specimen well(S), then add **3 drops of buffer (approximately 120µL) to the buffer well (B)**, and start the timer.
  - For **Whole Blood** specimen:
    - Use a **pipette**: To transfer **10µL of whole blood** to the specimen well(S), then add **3drops of buffer (approximately 120µL) to the buffer well (B)**.
    - Use a **dropper**: Hold the dropper vertically, draw the specimen about **1 cm above the upper end of the nozzle** and transfer **1 full drop (approx. 10µL)** of specimen to the sample well(S). Then add **3 drops of buffer (approximately 120µL) to the buffer well (B)**, and start the timer.
- Wait for the colored line(s) to appear. Read results at **10 minutes**. Do not interpret the result after **20 minutes**.

**Note:** It is suggested not to use the buffer, beyond 3 months after opening the vial.



### 【INTERPRETATION OF RESULTS】

**IgG POSITIVE: Two colored lines appear.** One colored line should always appear in the control line region (C) and another line should be in the IgG line region.

**IgM POSITIVE: Two colored lines appear.** One colored line should always appear in the control line region (C) and another line should be in the IgM line region.

**IgG and IgM POSITIVE: Three colored lines appear.** One colored line should always appear in the control line region (C) and two test lines should be in the IgG line region and IgM line region.

**\*NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of anti-Lyme antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

**NEGATIVE: One colored line appears in the control line region (C).** No line appears in the IgG region or the IgM region.

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

### 【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

### 【LIMITATIONS】

- The Lyme IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for detection of IgG and IgM antibodies to *Borrelia* in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to *Borrelia* can be determined by this qualitative test.
- The Lyme IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma) will only indicate the presence of IgG and IgM antibodies to *Borrelia* in the specimen and should not be used as the sole criteria for the diagnosis of Lyme infections.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of *Borrelia* infection.
- The hematocrit level of the whole blood can affect the test results.
- Hematocrit level needs to be between 25% and 65% for accurate results.

### 【EXPECTED VALUES】

The Lyme IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial ELISA Lyme IgG tests and Lyme IgM tests. The correlation between these two systems is over 98%.

### 【PERFORMANCE CHARACTERISTICS】

#### Sensitivity and Specificity

The Lyme IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) was compared with a leading commercial ELISA Lyme IgG tests and ELISA Lyme IgM tests; the results show that Lyme IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high sensitivity and specificity.

#### IgG Results

Lyme IgG/IgM Rapid Test for IgG	Method	ELISA		Total Results
	Results	Positive	Negative	
	Positive	21	1	
Negative	1	89	90	
Total Results		22	90	112

Relative Sensitivity: 95.5% (95%CI\*: 87.3%-100%)

Relative Specificity: 98.9% (95%CI\*: 97.1%-99.8%)

Accuracy: 98.2% (95%CI\*: 93.7%-99.8%)

\*Confidence Interval

#### IgM Results

Lyme IgG/IgM Rapid Test for IgM	Method	ELISA		Total Results
	Results	Positive	Negative	
	Positive	17	1	
Negative	1	89	90	
Total Results		18	90	108

Relative Sensitivity: 94.4% (95%CI\*: 72.7%-99.9%)

Relative Specificity: 98.9% (95%CI\*: 96.7%-100%)

Accuracy: 98.1% (95%CI\*: 93.5%-99.8%)

\*Confidence Interval

#### Precision

##### Intra-Assay

Within-run precision has been determined by using 3 replicates of five specimens: negative, IgG low positive, IgG high positive, IgM low positive, IgM high positive. The negative, low positive, and high positive values were correctly identified >99% of the time.

##### Inter-Assay

Between-run precision has been determined by 3 independent assays on the same specimens: negative, IgG low positive, IgG high positive, IgM low positive, IgM high. Three different lots of the Lyme IgG/IgM Rapid Test cassette (Whole Blood/Serum/Plasma) have been tested over a 3-days period using negative, low positive, and high positive specimens. The specimens were correctly identified >99% of the time.

#### Cross-reactivity

The Lyme IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for anti-HAV IgM, HBsAg, anti-HCV IgG, anti-HIV IgG, anti-RF IgG, anti-Syphilis IgG, anti-H. Pylori IgG, anti-Rubella IgG, anti-Toxo IgG, anti-HSV 1 IgG, anti-HSV 2 IgG, anti-CMV IgG, anti-Rubella IgM, anti-Toxo IgM, anti-HSV 1 IgM, anti-HSV 2 IgM and anti-CMV IgM positive specimens. The results showed no cross-reactivity.

#### Interfering Substances

The following compounds have been tested using the LymeIgM/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Genistic Acid: 20 mg/dL
Ascorbic Acid: 2g/dL	Albumin: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin 1000mg/dL
Bilirubin: 1g/dL	Oxalic Acid: 60mg/dL

### 【BIBLIOGRAPHY】

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- Jump up^Pritt, BS; Mead, PS; Johnson, DK; Neitzel, DF; RespcioKinyng, LB; Davis, JP; Schiffman, M; Sloan, LM; Schriefer, ME; Replogle, SM; Ray, JA; Bjork, J; Steward, CR; Deedon, A; Lee, X; Kingry, LC; Miller, TK; Feist, MA; Theel, ES; Patel, R; Irish, CL; Petersen, JM (5 February 2016). "Identification of a novel pathogenic *Borrelia* species causing Lyme borreliosis with unusually high spirochaetemia: a descriptive study". *Lancet Infect. Dis.* 16: 556–564.
- "Two-step Laboratory Testing Process".cdc.gov. 15 November 2011. Archived from the original on 12 March 2015. Retrieved 2 March 2015.
- Jump up^"Testing of Ticks".cdc.gov. 4 June 2013.Archivedfrom the original on 19 February 2015. Retrieved2 March2015.

#### Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions For Use



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