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Lyme IgG/IgM Rapid Test Kit (Colloidal Gold)

PRODUCT NAME
Lyme IgG/IgM Rapid Test Kit(Colloidal Gold)

SPECIFICATION
25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE
The Lyme IgG/IgM Rapid Test 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. 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. The rash is typically neither itchy nor painful. Approximately 25-50% of infected people do not develop a rash.1 Other early symptoms may include fever, headache and feeling tired. 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.1 Months to years later, repeated episodes of joint pain and swelling may occur.1 Occasionally, people develop shooting pains or tingling in their arms and legs. Despite appropriate treatment, about 10 to 20% of people develop joint pains, memory problems, and feel tired for at least six months.
Lyme disease is transmitted to humans by the bite of infected ticks of the genus Ixodes. Usually, the tick must be attached for 36 to 48 hours before the bacteria can spread. In North America, Borrelia burgdorferi and Borrelia mayonii are the causes. In Europe and Asia, the bacteria Borrelia afzelii and Borrelia garinii are also causes of the disease. The disease does not appear to be transmissible between people, by other animals, or through food. Diagnosis is based upon a combination of symptoms, history of tick exposure, and possibly testing for specific antibodies in the blood. Blood tests are often negative in the early stages of the disease.2 Testing of individual ticks is not typically useful.

PRINCIPLE
The Lyme IgG/IgM Rapid Test 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, antihuman 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 nantibodies, 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.

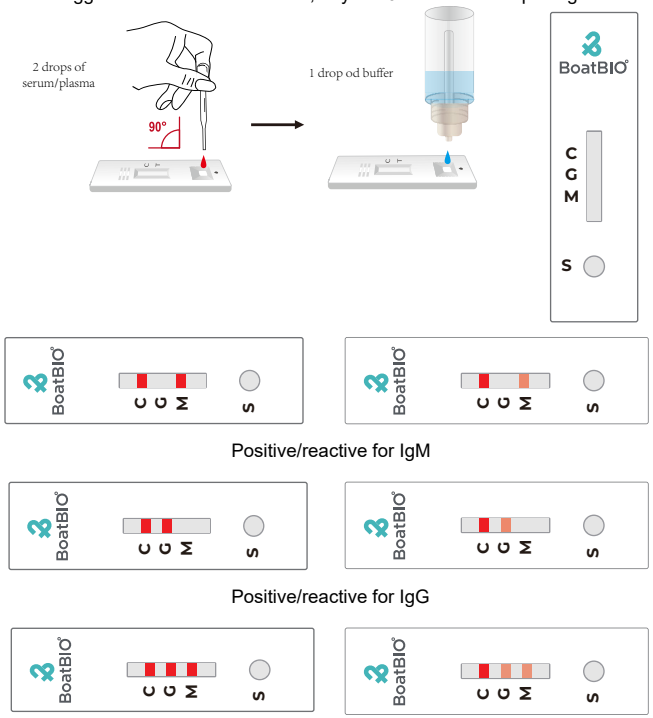
MATERIALS
Materials provided
• Test Cassettes • Specimen collection tubes with extraction buffer
• Package insert
Materials Required but Not Provided
• Specimen collection containers • Pipette and disposable tips (optional)
• Centrifuge • Timer • Droppers

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

STORAGE AND STABILITY
Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. DO NOT FREEZE. Do not use beyond the expiration date.
NOTE: Once the canister has been opened, the remaining test(s) are stable for 90 days only.

SPECIMEN COLLECTION AND PREPARATION
The Lyme IgG/IgM Rapid Test 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 10pL. 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. Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

DIRECTIONS FOR USE
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
1.Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. 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.
3.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.
fingerstick whole blood specimen to the specimen well (S) of test devices, then add 1 drop of buffer (approximately 40 μL) and start the timer. See illustration below.
3.Wait for the colored line(s) to appear. Read results at 10 minutes by comparing the T line intensity with provided color card. Do not interpret the result after 20 minutes.
Note: It is suggested not to use the buffer, beyond 6 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

I.The Lyme IgG/IgM Rapid Test 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.
2. The Lyme IgG/IgM Rapid Test 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.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. 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.
5. The hematocrit level of the whole blood can affect the test results.
6. Hematocrit level needs to be between 25% and 65% for accurate results.

EXPECT VALUE

The Lyme IgG/IgM Rapid Test 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 CHARACTERISTICSIntra-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 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 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 LymeIgG/IgM Rapid Test (Whole Blood/Serum/Plasma) and no interference was observed.

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

INDEX OF SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
	Batch code		In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don’t use the product when the package is damaged		Keep dry
	Date of manufacture		Tests per kit
	CE Mark		Biological Risks
	Authorized representative in the European Community		

BASIC INFORMATION

Ningbo BESTest Bio-technology Co.,Ltd.
Address: No.80 building, No.777, Qing Feng Road, Cicheng Town,Jiangbei District, Ning Bo, Zhejiang, China 315033
Tel: 0086 571 2799 8736

CMC MEDICAL DEVICES & DRUGS S.L
Address: C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain
Tel: +34951214054
Email - info@cmcmedicaldevices.com