Brucella IgG/IgM Rapid Test

Cat. No.: S023-04

In vitro Diagnostics

INTENDED USE

Brucella IgG/IgM Rapid Test Kit is a qualitative immunochromatographic assay for the detection of IgG and IgM antibodies produced against Brucella in human blood/ Serum. Brucella IgG/IgM Rapid Test is only intended for initial screening and reactive samples should be confirmed by a supplemental assay such as ELISA.

SUMMARY & TEST DESCRIPTION

Brucellosis is an infectious disease that occurs from contact with animals carrying Brucella bacteria. Brucellosis is a zoonosis caused by Brucella abortus, B.suis and B.melitensis. Clinical manifestations of brucellosis in humans are variable and often are non-specific, and the diagnosis requires confirmation by laboratory testing. Brucellosis is a highly contagious zoonosis caused by ingestion of unsterilized milk or meat from infected animals or close contact with their secretions. Human brucellosis is a disease that is found worldwide, and it has an annual occurrence rate of more than 500,000 cases.

Brucella spp. are small, Gram-negative, non-motile, non-spore-forming, rod shaped (coccobacilli) bacteria. They function as facultative intracellular parasites causing chronic disease, which usually persists for life. Symptoms include profuse sweating and joint and muscle pain. Brucellosis has been recognized in animals including humans since the 20th century.

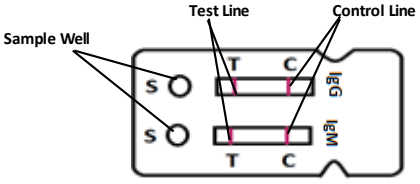
Brucella IgG/IgM Rapid Test is a Combo device which contains two test lines. Both the Test lines utilizes Brucella LPS Antigen as the capture molecule. Anti-Human IgG-CGC is used as the detection antibody for Brucella IgG rapid test and Anti Human IgM-CGC as the detection antibody for Brucella IgM rapid test. The captured antigens are detected using colloidal gold conjugate.

TEST PRINCIPLE

Brucella IgG-IgM Rapid Test works on chromatographic immunoassay. Basic components of each test strip includes:

Brucella IgG: a) Conjugate pad which contains Anti-Human IgG colloidal gold conjugate; b) a nitrocellulose membrane strip containing test line, T : Brucella LPS Antigen, C: Goat Anti- Mouse.

Brucella IgM: a) Conjugate pad which contains Anti-Human IgM colloidal gold conjugate; b) a nitrocellulose membrane strip containing test line, T : Brucella LPS Antigen, C: Goat Anti- Mouse.



Test sample that is added to the sample well (S), with adequate amount of buffer migrates from the sample pad along the conjugate pad where Brucella specific IgG/IgM present in the sample will bind to Colloidal Gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zones where the complex accordingly will bind to the immobilized Brucella LPS Ag (on test line) producing a visible line on the membrane. If the respective antibody is not present in the sample, no reaction occurs in the capture zones and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

REAGENTS & MATERIALS PROVIDED

1. Each Kit contains 10 test devices, each sealed in a foil pouch containing following items:
   a. One combo card
   b. Desiccant
2. Assay Diluent- In dropper bottle
3. Instruction Leaflet

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTIONS & WARNING

1. Use within 10 minutes after opening pouch.
2. Do not touch result window.
3. Use only the buffer supplied along with the kit.
4. Do not mix components from different kits.
5. Use only for in-vitro diagnostic purpose.

SAMPLE COLLECTION & PREPARATION

- **Blood Specimen:** Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.
- **Serum:** Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulates, centrifuge the blood to get serum specimen as supernatant.

Note:

- If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.
- For storage period longer than 5 days, freezing is recommended. Store at -20^{0}C
- The specimen should be brought to room temperature prior to use.

Treat the specimen as infectious and handle with standard biosafety measures.

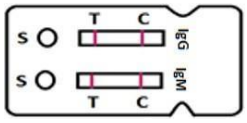
TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 10µl of Whole Blood/Serum to the Sample well "S"
3. When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the sample hole.
4. Wait for 10 minutes and interpret results. The result is considered invalid after 15 minutes All results where control band does not appear are considered invalid.

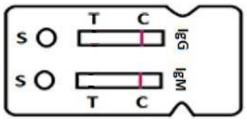
INTERPRETATION OF TEST RESULT

(IMPORTANT NOTE: INTERPRET THE RESULTS WITH RESPECT TO THE WRITINGS "C" & "T" ON THE DEVICE AS SHOWN BELOW)

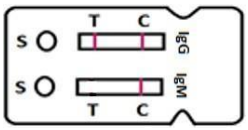
A) IgG and IgM Positive



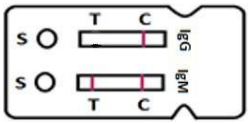
B) IgG and IgM Negative



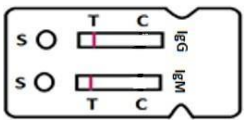
C) IgG Positive and IgM Negative



D) IgG Negative and IgM Positive



D) INVALID: No Control Line



Reference:

1. Mohammedreza R. HasanjaniRoushana, M.J. SoleimaniAmina, Theresia H. Abdoelb, Henk L. Smits. Application of a user-friendly Brucella-specific IgM and IgG antibody assay for the rapid confirmation of Rose Bengal-positive patients in a hospital in Iran. Transactions of the Royal Society of Tropical Medicine and Hygiene (2005) 99, 744—750.
2. Hasan Irmak, TuranBuzgan, Omer Evirgen et al. Use of the BrucellaIgM and IgG flow assays in the serodiagnosis of human brucellosis in an area endemic for brucellosis. Am. J. Trop. Med. Hyg., 70(6), 2004, pp. 688–694

Manufactured by

ubio Biotechnology Systems Pvt Ltd
Plot # 15A,Biotechnology Zone
Kalamassery, Cochin, Kerala, India 683503
Ph:, +91-484-2970043
https://www.ubio.in|
email: contact@ubio.co.in

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