Test-it™ Brucella IgM / IgG Lateral Flow Assay
Brucella-specific immunoassay for use with human serum or whole blood samples

Product Codes
IgM: BRU001
IgG: BRU002

Intended Use
Life Assay manufactures the Test-it™ range of Brucella IgM and IgG lateral flow assays for serodiagnosis of brucellosis in humans. The Brucella IgM lateral flow assay is designed for the detection of Brucella-specific immunoglobulin M (IgM) antibodies, and the Brucella IgG lateral flow assay is designed for the detection of Brucella-specific IgG antibodies.

Introduction
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. Test-it™ Brucella IgM and IgG lateral flow assays provide an indirect measure for infection through the detection of specific antibodies. Specific IgM antibodies usually predominate early in the disease. Specific IgG antibodies may remain present for a much longer period and predominate in persistent infections and during relapse. Test-it™ Brucella IgM and IgG lateral flow assays are relatively simple and rapid assays. The assays do not require special training, equipment, or electricity. Results are obtained in 15 minutes. The assays and the running fluid can be stored at +4°C to +28°C.

Principle
The Test-it™ Brucella lateral flow assay is a one step immunochromatographic lateral flow assay. A lipopolysaccharide antigen (LPS) prepared from a culture of B. abortus is immobilised in a discrete line on a porous nitrocellulose membrane located in the test zone. The assay utilises a dried detection reagent deposited within the device. The mobile detection reagent consists of anti-human antibodies labelled with red colloidal gold particles. To perform the assay a serum sample is placed in the sample port. Running fluid is added to solubilise the detection reagent and to carry the serum molecules and detection reagent through the porous membrane in the test zone. Antibodies in the serum that are specific for Brucella attach to the LPS antigen and these antibodies will be stained by binding of the detection reagent. The presence of specific IgM antibodies will be revealed by the appearance of a red line in the test zone in the Brucella IgM lateral flow assay. A red line will appear in the test zone in the Brucella IgG lateral flow assay when specific IgG antibodies are present. If the sample does not contain Brucella-specific IgM or IgG antibodies, the sample and detection reagent will pass over the test zone and no line will appear in the test zone. With any sample a red line should appear in the control zone. The control ensures that the detection reagent is still active.

Test Kit and Labelling
Test-it™ Brucella IgM and IgG lateral flow assays are supplied as separate kits. The individual devices are marked as IgM or IgG. Each kit contains 25 individually foil sealed assay devices together with 1 bottle of running fluid, sufficient for the analysis of 25 serum or whole blood samples. Micropipettes for application of whole blood or serum. Lancets and Alcohol swabs.

Utensils Not Provided
Stopwatch or timer.

Storage
Test-it™ Brucella lateral flow kits should be stored at +4°C to +28°C, in a dry place and protected from direct exposure to sunlight for optimal performance. Individual devices may be stored up to +50°C for short periods.

Expiry Date
The expiry date is printed on the packaging. When stored properly the shelf life is up to two years from the date of manufacturing.

Precautions
Blood and serum samples should be handled with care as they are potentially infectious. Equipment and supplies for specimen handling should be treated accordingly. Used assay devices, disposables and samples should be properly decontaminated and discarded.

Specimen Collection
Serum should be prepared in the same way as routinely performed for any serological assay. Freshly collected samples should be used. Serum samples stored at -20°C may be used as well. Whole blood samples may be collected using an anticoagulant such as EDTA, heparin or citrate. Alternatively for a finger prick sample, clean the patient’s finger with the alcohol swab making sure the alcohol is dry before pricking with the lancet provided.
Standard Assay Procedure
1. Remove a Test-it™ Brucella lateral flow assay device from the packaging and place on a bench top with the test window facing upwards. Write patient’s identity in space provided to the left of the result window.
2. Immediately check if desiccant is still orange in colour. If desiccant has turned green, the test has been exposed to moisture and the test must be discarded.
3. Using the plastic pipette provided draw up serum or whole blood to the first marked line of the plastic pipette (5 µl) and spot to the oval sample port ($).
4. Immediately add 3 drops of running fluid to the oval sample port ($).
5. You will see the reagent moving across the result window. This shows that the test is working.
6. Read results at 15 minutes. Results are stable for a further 15 minutes; thereafter false results may occur.

Interpretation of Test Results
A. Test-it™ Brucella IgM lateral flow assay
   Positive Result: Indicated by the presence of a line at the test zone (T) and a line at the control zone (C). In brucellosis, specific IgM antibodies usually are present during the first few months of illness. Specific IgM antibodies generally are not present in patients with persisting brucellosis. A positive result in the Test-it™ Brucella IgM lateral flow assay is consistent with acute brucellosis. Specific IgM antibody levels rapidly decline after treatment.
   Negative Result: Indicated by absence of a line at the test zone (T) and presence of a line at the control zone (C).

B. Test-it™ Brucella IgG lateral flow assay
   Positive Result: Indicated by the presence of a line at the test zone (T) and a line at the control zone (C). Specific IgG antibodies develop shortly after infection and may remain present months to years after infection. A positive result in the Test-it™ Brucella IgG lateral flow assay is consistent with active brucellosis. Specific IgG antibodies also may be formed during relapse.
   Negative Result: Indicated by absence of a line at the test zone (T) and presence of a line at the control zone (C).

In some patients specific IgM and IgG antibodies may be present at the same time. In other patients only one of these two antibody species may be present. Test-it™ Brucella IgM and IgG lateral flow assays are complementary assays and the use of both tests simultaneously increases sensitivity.

Limitations of Use
The sensitivity and specificity of the Test-it™ Brucella lateral flow assays depend on various factors including stage of disease and previous antibiotic usage.

SPECIAL NOTE:
The intensity of the Control line (C) may vary from test to test. A weak or faint Control line (C) does not disqualify the test and has no influence on the validity of the test result (T) whatsoever.

Recommended Literature

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