



# BRUCELLA MELITENSIS MACRO

Determination of antibodies associated with Brucella Melitensis infections by coloured bacterial suspension in test-tube

## TEST SUMMARY

The Antibodies associated with Brucella Melitensis infections cause agglutination of inactive bacteria present in suspension. The intravital colouring permits an easier reading of agglutination formation.

## SAMPLES

Serum.  
Stability 6 days at 4°C.

## REAGENTS

Suspension: Coloured intravital inactive bacterial suspension; conservative and stabilizer.

## REAGENTS PREPARATION

Reagents are ready for the use.  
The bacterial suspension must be resuspended with much care, shaking many times by inversion.  
Stability: the components of this kit will remain stable until the expiration date stated on the label, when stored at 2-8°C. Do not freeze.

## MATERIAL REQUIRED BUT NOT SUPPLIED

Physiologic solution. Automatic micropipette.  
Normal laboratory equipment.

## PRECAUTIONS

Reagent may contain not reactive and conservative components. It is opportune to avoid contacts with the skin and do not swallow.  
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

## PROCEDURE

In a 8 tubes serie (12 x 100 mm) dilute the serum in the first 7 with physiologic solution as indicated in the following table. Using the same pipette (inspiring and discharging many times) mix carefully content of the second tube and transfer 500 µl in the following tube etc. Discharge 500 µl from last tube (tube n°7).

| Test-tubes                           | 1      | 2             | 3             | ... | 7             | Susp. Contr. |
|--------------------------------------|--------|---------------|---------------|-----|---------------|--------------|
| Physiologic                          | 900 µl | 500 µl        | 500 µl        | ... | 500 µl        | 500 µl       |
| Sample                               | 100 µl | 500 µl from 1 | 500 µl from 2 | ... | 500 µl from 6 |              |
| Discharge 500 µl from last test-tube |        |               |               |     |               |              |
| Bacterial suspension                 | 500 µl | 500 µl        | 500 µl        | ... | 500 µl        | 500 µl       |
| Titre                                | 1:20   | 1:40          | 1:80          | ... | 1:1280        |              |

Shake tubes by a sweet movement. Incube at 37°C for 16-18 h or at 22°C for 2 days.

## RESULTS INTERPRETATION

Being given the intravital colouring of suspension, it's possible to effect a preliminary reading without shake the tubes:

A coloured bottom with a clear point shape, on the tube bottom, indicates negativity.

An agglutinate that cover all the tube bottom indicates a clear positivity, while, a no uniform agglutinate with a bottom in the centre, on the tube bottom, indicate a feeble positivity.

The serum titre is given by a high dilution in which there is a feeble positivity.

Proceed then with a light shaking of tubes:

Shake before the 8<sup>th</sup> tube (suspension control) to can characterize the suspension, then shake tubes that contain the sample and value the precipitate's behaviour as regards that of suspension's control. The negativity is given by absence of agglutinates (the same behaviour as regards that suspension's control), positivity shows, on the contrary, the presence of agglutinates always as bigger as the positivity is greater.

The agglutination of somatic component has an uncouth appearance and persists also after the shaking, while the ciliary component has a flaky appearance and tends to dissolve by shaking.

The serum titre is given by a higher dilution in which there is a feeble positivity.

## DIAGNOSTIC VALUES

Titres until 1:40 are considered negative; from 1:80 to 1:160 are suspect, and from 1:320 are positive.

It is a distinctive sign for the infection diagnosis the significant increase of titre between examined samples after some days.

## NOTES

- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.

## CALIBRATION/QUALITY CONTROL

It's advisable the execution of a quality internal control. In order to do this, are available by request the following control sera .

**BS00011** 3 x 0,5 ml  
Positive Control Salmonella, Brucella, Proteus

## TEST PERFORMANCE

### Sensitivity

In presence of high antibodies titres, phenomenon of prozone can happen, therefore positivity is absent for low dilutions also being present for higher dilutions.

### Specificity

A comparison with an available commercial method gave following results on 50 samples compared, giving a specificity = 100%.

| COMPETITORS | LTA srl |    |    | TOT. |
|-------------|---------|----|----|------|
|             |         | +  | -  |      |
|             | +       | 17 | 0  | 17   |
|             | -       | 0  | 33 | 33   |
|             | TOT.    | 17 | 33 | 50   |

## WASTE DISPOSAL

Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

## PACKAGING

### CODE MA00920

Brucella Melitensis macro suspension 1 x 20 ml

### CODE MA00925

Brucella Melitensis macro suspension 5 x 20 ml

## REFERENCES

Widal F. – Bull. Men. Soc. Med. Hop de Paris – 6; 26 (1986).  
Rose N.R., Friedman H. – Manual of clinical Immunology – American Society for Microbiology, II ed.

## MANUFACTURER

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## SYMBOLS

- Only for IVD use
- Lot of manufacturing
- Code number
- Storage temperature interval
- Expiration date
- Warning, read enclosed documents
- Read the directions
- Biological risk

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