

BRUCELLA WRIGHT

REF 63241

DETECTION OF ANTI-*BRUCELLA* ANTIBODIES



881167 - 2014/11

BIO-RAD

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1- CLINICAL INTEREST

Wright's serological test allows serological diagnosis of acute brucellosis. This quantitative test becomes positive early, as of the 10th or 12th day, during the course of acute brucellosis, but rapidly becomes negative because it detects IgM. It is sometimes negative in some patients with subacute brucellosis and in most of those with chronic brucellosis. Consequently, it is not a recommended tool for screening or for epidemiological studies.

2- PRINCIPLE

The test is based on agglutination of a suspension of *Brucella* killed by exposure to formaldehyde and heat. A titre equal to or greater than 1/80 (120 IU/ml) indicates active brucellosis. Lower titres (1/40 or even 1/20) indicate suspicion of brucellosis.

Blocking antibodies and zone phenomenon, frequently, can be responsible for false negative results. Antigenic similarities can lead to false positive results.

3- PRODUCT INFORMATION

- **Presentation** : 1 ampoule of 10ml

Label	Reagents
Brucella Wright	Brucella antigen for Wright serological diagnostic (suspension of <i>Brucella</i> killed by exposure to heat and 4% formaldehyde)

- **Storage** : at + 2-8 °C.
- **Shelf-life** : until the expiry date printed on the package in absence of microbial contamination (even once opened).

4- PRECAUTIONS

The reliability of the results depends on correct implementation of the following Good Laboratory Practices:

- Before use, allow reagents to reach room temperature (18 - 30°C).
- Do not use expired reagents.
- Use glassware washed and rinsed with distilled water or preferably disposable material.
- Use a new pipette tip for each sample.

Health and safety instructions

Wear disposable gloves when handling reagents.

- Do not pipette by mouth.
- Any material that comes directly in contact with samples, should be considered as if capable of transmitting infectious disease.
- Avoid samples from spilling.
- For hazard and precaution recommendations related to some chemical components in this test kit, please refer to the pictogram(s) mentioned on the labels and the information supplied at the end of instruction for use. The Safety Data Sheet is available on www.bio-rad.com.

5- SPECIMEN

1. Serum collected on dry tubes is the recommended sample type.
2. Observe the following recommendations for the handling, processing, and storing serum samples:
 - Collect all serum samples observing routine precautions.
 - Allow samples to clot completely before centrifugation.
 - Keep tubes stoppered at all times.
 - After centrifugation separate the serum and store it in a tightly stoppered storage tube.
 - The specimens can be stored at +2-8°C if screening is performed within 24 hours.
 - If the assay will not be completed within 24 hours, or for shipment of samples, freeze at -20°C, or colder.
 - Preferably, thaw samples once only. Previously frozen specimens should be thoroughly mixed after thawing prior to testing.
3. Interferences due to high levels of albumin or bilirubin are unknown. Do not use lipemic or hemolyzed samples.
4. Do not heat the samples.

6- PROCEDURE

A- MATERIALS REQUIRED NOT PROVIDED

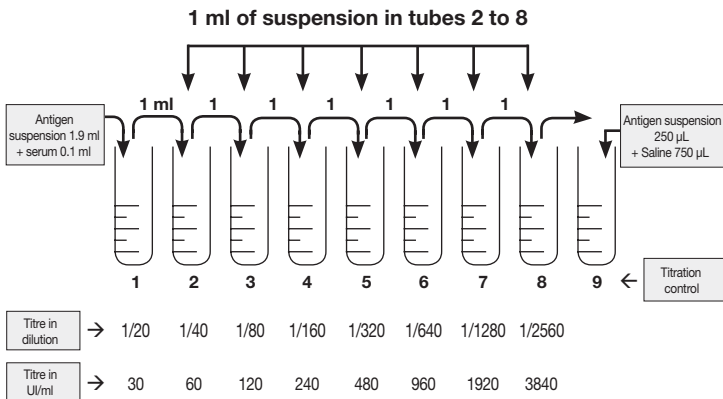
- Vortex mixer.
- Incubator
- Physiological water.
- Automatic or semi-automatic, adjustable or preset, pipettes or multi-pipettes to measure and dispense 10 to 1000µl and 1, 2 and 10 mL.
- Hemolysis tubes.

B- DILUTION OF SERUMS

Dilutions of the test serum are prepared using the bacterial suspension as the diluent.

- Place nine perfectly clean hemolysis tubes (5 ml if possible) on a rack.
- Introduce 1.9 ml of antigen suspension + 0.1 ml of test serum into the first tube. Homogenise.
- Introduce 1 ml of antigen suspension into each tube, numbered from 2 to 8 and 250 μ l in tube n° 9.
- Take 1 ml from the first tube (containing the 1/20 dilution of the test serum) and transfer to tube n°2. Homogenise.
- Take 1 ml from tube n°2 and transfer to tube n°3. Homogenise.
- Repeat this procedure until tube n°8 inclusive. Discard the 1ml sample removed from tube n°8.

Introduce 750 μ l of saline into tube n°9, which constitute the titration control.



C- INCUBATION

Incubate in an incubator at 37°C for 18 to 24 hours after sealing the tubes (stopper, parafilm). If necessary, incubation can be replaced by centrifugation for 5 minutes at 250 g.

D- READING

Examine the tubes, without disturbing their contents, against a black background, placing a light source above and behind the tubes.

- First verify that there is no agglutination in the titration control tube.
- Several types of agglutination can be seen:
 - pancake-like agglutination in the bottom of the tube with a clear supernatant (+++)
 - clearly visible agglutinates in a slightly cloudy fluid (++)
 - agglutinates visible only on examination with an agglutinoscope (+).

The absence of agglutination indicates a negative test (-).

If the test is positive, the antibody titre in the test serum corresponds to the highest dilution yielding a degree of cloudiness similar to that seen in the titration control tube.

7- INTERPRETATION OF RESULTS

- A titre equal to or greater than 1/80 (120 IU/ml) indicates active brucellosis : titres are usually higher than these cut-off levels.
- Lower titres (1/40 or even 1/20) indicate suspicion of brucellosis and the serologic test should be repeated several days after.

8- PERFORMANCES / QUALITY CONTROL OF THE TEST

Brucella Wright performances are controlled using Brucella serum control (code 63240).

This positive control serum gives an agglutination reaction with the antigen whereas it stays homogenous with negative serum (absence of agglutination)

9- QUALITY CONTROL OF THE MANUFACTURER

All manufactured reagents are prepared according to our Quality System, starting from reception of raw material to the final commercialization of the product. Each lot is submitted to quality control assessments and is only released to the market, after conforming to pre-defined acceptance criteria. The records relating to production and control of each single lot are kept within Bio-Rad.

10- LIMITATIONS

1. A negative test can be due to the presence of blocking antibodies (IgA, IgG), which can be detected by adding 20 µl of positive control *Brucella* serum (code 63240) to tube n°3. After incubation at 37°C for 18 hours, the absence of agglutination indicates the presence of blocking antibodies in the test serum.
2. The *Brucella* agglutination test is negative during the first ten to 15 days after onset of brucellosis. Longer negative phases can occur in young pediatric patients. A few patients never develop agglutinating antibodies during the disease.
3. The test is sometimes positive at a titre of 1/20 (30 IU/ml) or 1/40 (60 IU/ml) in symptom-free subjects living in highly endemic areas. In these subjects, and in patients with a history of brucellosis, agglutinating antibody titres sometimes rise transiently in the event of infection with *Yersinia enterocolitica* or *Francisella tularensis* or after cholera immunisation (these are non specific cross-reactions).

Most doubtful cases can be resolved by repeating the antibody agglutination test.

11- REFERENCES

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- (EE)** • Käesolev toode sisaldab inim-või loomseid komponente. Käsitseta ettevaatlikult.
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- (GR)** • Αυτό το προϊόν περιέχει ανθρώπινα ή ζωικά στοιχεία. Χειριστείτε το με προσοχή.
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- (LT)** • Šiame produkto yra žmogiškosios arba gyvūninės kilmės sudedamosios dalys. Elgtis atsargiai.
- (NL)** • Dit product bevat menselijke of dierlijke bestanddelen. Breekbaar.
- (NO)** • Dette produktet inneholder humane eller animalske komponenter. Håndteres med forsiktighet.
- (PL)** • Niniejszy produkt zawiera składniki pochodzenia ludzkiego lub zwierzęcego. Należy obchodzić się z nim ostrożnie.
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- (RO)** • Acest produs conține materiale de origine umană sau animală. Manevrați-l cu grijă.
- (SE)** • Denna produkt innehåller beståndsdelar från människa eller djur. Hantera produkten varsamt.
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- (SK)** • Tento výrobok obsahuje ľudské alebo zvieracie zložky. Narábajte s ním opatrne.

H333

(BG)

внимание
Може да причини вреда при вдишване.

(CZ)

Varování
Může škodit zdraví při vdechnutí.

(DE)

Achtung
Kann beim Einatmen gesundheitsschädlich sein.

(DK)

Advarsel
Kan være sundhedsskadelig ved indånding.

(EE)

Hoiatus
Kahjulik sissehingamisel.

(EN)

Warning
May be harmful if inhaled.

(ES)

Atención
Puede ser nocivo si se inhala.

(FI)

Varoitus
Mahdollisesti haitallinen hengitettynä.

(FR)

Attention
Peut être nocif par inhalation.

(GR)

Προσοχή
Πιθανά βλαβερό κατά την εισπνοή.

(HR)

Upozorenje
Može štetno ako se udiše.

(HU)

Figyelem
Belélegzés esetén veszélyes lehet.

(IT)

Attenzione
Può essere nocivo per inalazione.

(LT)

Atsargiai
Gali būti kenksminga įkvėpus.

(NL)

Waarschuwing
Kan schadelijk zijn bij inademing.

(NO)

Advarsel
Kan være helsefarlig ved innånding.

(PL)

Uwaga
Może działać szkodliwie przez drogi oddechowe.

(PT)

Atenção
Pode ser nocivo em caso de inalação.

(RO)

Atenție
Poate fi nociv dacă este inhalat.

(SE)

Varning
Kan vara skadlig att inandas.

(SI)

Pozor
Možna nevarnost trajnih okvar zdravja pri vdihavanju.

(SK)

Pozor
Môže byť škodlivé pri nadýchaní.



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