N.S. BIO-TEC

Brucella- A / M

REF: BRM -MA-100 (5 Ml)
BRA -MA-100 (5 Ml)
BRAM -MA-050 (2 X 2.5 Ml)
BRAM-MA-100 (2 X 5 Ml)

INTENDED FOR USE:

For the quantitative determination of Brucella abortus (Brucella-A), and Brucella melitensis (Brucella-M).

PRINCIPLE:

The smooth, attenuated stained Brucella antigen suspensions are mixed with the patient's serum. Specific antibodies to Brucella antigens if present in the patient serum will react with the antigen suspension to produce an agglutination reaction. No agglutination indicates the absence of specific antibodies to Brucella antigens Human Brucellosis (Diumal, or undulant fever) is a common febrile illness caused by infection with bacteria of some of the Brucella species (abortus, melitensis). This undulant fever, sweats and anorexia. On exposure the body responds to this antigenic stimulation by producing specific antibodies whose titres rise slowly at early stages and then increases. Specific antibodies to the Brucella spcies are detectable a few weeks after exposure and are of considerable importance in the diagnosis of Brucellosis.

SPECIMEN COLLECTION:

(1) No special preparation of patient is required prior to sample collection by approved techniques. Do not use hemolysed serum samples.
(2) Clean and dry glassware free from detergents must be used for sample collection.
(3) Do not heat inactivate the serum
(4) Though freshly collected serum is preferred, samples can be stored at 2-8°C, for 24 hours or frozen for 8 days should a delay in testing occur.

REAGENT COMPOSITIONS :

The Brucella-A / Brucella-M reagents contain ready to use standardized, attenuated, stained, smooth specific antigen suspensions of Brucella having specific reactivity towards antibodies to Brucella abortus (Brucella-A), and Brucella melitensis (Brucella-M).

PACKAGE: COLLECTION AND STORAGE.

Store in refrigerator (+2-8°C). Stable until the expiration date reported upon the package. After the unsealing and the taking of the reagent ,it is advised to close up the bottle immediately in order to avoid evaporation, direct light exposure and bacterial contamination

PRECAUTIONS & WARNING :

Avoid pipette with mouth. The preparation, according to current regulation, is classified as not dangerous. The total concentration of non active components (preservatives, detergents, stabilizers) is below the minimum required for citation. Anyway handle with care, avoid ingestion, avoid contact with eyes, skin and mucous membranes. The samples must be handle as potentially infected from HIV or Hepatitis.

REAGENT PREPARATION & STABILITY :

Store the reagent at 2-8°C. DO NOT FREEZE. The shelf life of the reagents is as per the expiry date mentioned on the reagent vial labels. Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity, and performance .

REQUIRED MATERIALS NOT PROVIDED:

General Laboratory Equipment and instrumentations.

PROCEDURE:

Bring all reagents into room temperature. Shake and mix the Brucella antigen suspensions well before dispensing. The procedure for Brucella-A and for Brucella-M is identical.
(1) Take 8 test tubes and label them 1 to 8.
(2) Pipette 1.9 ml of isotonic saline or preferably 0.25% phenol saline to tube No.1.
(3) To each of the remaining tubes (2-7) add 1.0 ml of isotonic saline or preferably 0.25% phenol saline.
(4) To the tube No. 1 add 0.1 ml of serum sample to be tested. Mix well.
(5) Transfer 1.0 ml of the diluted serum from tube No. 1 to tube No. 2 and mix well.
(6) Transfer 1.0 ml of the diluted serum from tube No. 2 to tube No. 3 and mix well. Continue this serial dilution till tube No. 7.
(7) Discard 1.0 ml of the diluted serum from tube No.7
(8) Pipette 1.0 ml of isotonic saline in tube No. 8, which serves as a negative control.
(9) To all the tubes add 1 drop of appropriate Brucella antigen suspensions and mix well.
(10) Cover the tubes and incubate at 37°C for 24 hours.
(11) Observe for agglutination macroscopically in each tube of the dilution series.

QUALITATIVE METHOD

1. Place one drop of Positive control (available as Brucella Positive Control) onto the reaction circle of glass slide.
2. Place ~ 80µl of saline onto the next reaction circle of the glass slide.
3. Place ~ 80µl of patient serum to be tested onto the next reaction circle.
4. Add one drop of the appropriate Brucella antigen suspensions in each of the above circle.
(Containing positive control, saline, and the patient serum to be tested.)
5. Mix Contents of each circle uniformly over the entire circle with separate mixing sticks.
6. Gently rock the slide back and forth, observe for agglutination macroscopically, at one minute against white background.

SEMI-QUANTITATIVE METHOD

1. Using a pipette place 80µl, 40µl, 20µl, 10µl, and 5µl of patient serum to be tested on 5 different circles on the glass slide. The corresponding titres obtained will be 1:20, 1:40, 1:80,1:160 and 1:320 respectively

2. Place one drop of appropriate Brucella antigen suspension to each circle.

3. Mix contents of each circle uniformly over the entire circle with separate mixing sticks.

4. Gently rock the slide back and forth, observe for agglutination macroscopically at one minute against a white background.

WASTE DISPOSAL:

The disposal of the product must be in accordance with local regulation concerning waste disposal.

LIMITATIONS :

(1) Turbid and contaminated serum should not be used for testing.

(2) In the semi quantitative test the reactions obtained are roughly equivalent to those which occur in a tube test.

(3) Agglutinins are found in high proportion of normal individuals and titres less than 1:80 are of doubtful significance. A rising titre is more significant than a single high titre.

(4) False positive reactions may occure in sera of patients infected with Pasteurella tularensis or vaccinated with vibrio Cholerae.

(5) False positive results are likely if the test is read more than one minute after mixing on slide test.

(6) It is recommended that results of the tests should be correlated with the clinical findings to arrive at the final diagnosis.

(7) Prozoning may sometimes be encountered in serum containing very high titres on slide test.

(8) Since techniques and standardization vary from laboratory to laboratory one tube difference in titres can be expected.

REFERENCES:

1. J. G. Collee, J.P. Duguid, A G Fraser. Practical Medical Microbiology, 13 th Ed.: 525 – 530. 2. G.Galton, L.M.Jones, R.D. Angus, J.M. Verger. Techniques for the brucellosis laboratory Paris,1988.

	Consult Instruction for Use
	Caution Consult Accompanying Documents
IVD	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative In The European Community
REF	Catalogue Number
LOT	Batch Code
	Use By

N.S BIOTEC
MEDICAL EQUIPMENTS
66 Port Said St., Camp Shezar
Alexandria – Egypt
Tele: 002 03 592 0902
Fax : 002 03 592 0908
Website : www.nsbiotec.com
E- mail : info@nsbiotec.com

CE
EC REP
CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo, 18.
29006. Málaga, Spain