Cenogenics

ROSE BENGAL BRUCELLA ANTIGEN

IVD CE

INTENDED USE

CENOGENICS' ROSE BENGAL BRUCELLA ANTIGEN is a bacterial suspension for use in the slide agglutination test to detect the presence of bacterial agglutinins associated with Brucella infections or previous exposure.

PRINCIPLES OF THE PROCEDURE

When viable bacteria are introduced into a susceptible host, an immune response generally occurs. This immune response results in the production of antibodies called agglutinins. The principle of the test is an immunological reaction (agglutination) between the antibodies produced to the viable bacteria (agglutinins) and the corresponding bacterial antigen.

MATERIALS PROVIDED

FOR CATALOG NO. FA-43 AND FA-44

ROSE BENGAL BRUCELLA ANTIGEN: Concentrated Brucella abortus, strain 1119-3, suspended in a buffered diluent and stained with Rose Bengal Dye.

Product instructions

FOR CATALOG NO. FK-45

ROSE BENGAL BRUCELLA ANTIGEN: Concentrated Brucella abortus, strain 1119-3, suspended in a buffered diluent and stained with Rose Bengal Dye.

BRUCELLA POSITIVE CONTROL: Stabilized diluted rabbit serum containing antibodies to Brucella antigen.

BRUCELLA NEGATIVE CONTROL: Stabilized diluted human serum nonreactive for Brucella antigen.

6-Well white slide

Product instructions

MATERIALS REQUIRED BUT NOT PROVIDED

Pipets for dispensing patient serum

Mixing Sticks

Timer

STORAGE
Store all reagents at 2°-8°C. Do not freeze.

PRESERVATIVES
ROSE BENGAL BRUCELLA ANTIGEN: Preserved with 0.5% phenol. BRUCELLA POSITIVE CONTROL: Preserved with sodium azide, 0.1%. BRUCELLA NEGATIVE CONTROL: Preserved with sodium azide, 0.1%

PRECAUTIONS
1. The source material from which the negative control was prepared was tested and found to be nonreactive for HBsAg, HCV and HIV. No known method can offer assurance that the product derived from human blood will not transmit infectious agents. HANDLE AS IF CAPABLE OF TRANSMITTING INFECTIOUS DISEASE.
2. For in vitro diagnostic use.
3. The Brucella positive and negative controls contain sodium azide as a preservative. This material is known to form explosive mixtures in the presence of lead compounds. Use copious amounts of water to rinse slides after completion of the test.
4. Do not use reagents after the expiration date.

SPECIMENS
Use freshly collected serum. The serum specimen should be stored refrigerated. If the testing is to be prolonged in excess of 24 hours, serum should be frozen. Bacterial contamination may cause protein denaturation. All sera to be tested should be clear and free of bacterial contamination.

REAGENT PREPARATION
Rose Bengal Brucella antigen and controls are ready to use. No preparation is required.

PROCEDURE
1. Bring reagents and serum specimens to room temperature.
2. Deliver 30µl of the serum sample to a circle on the white slide. Use a clean pipet (or pipet tip) for each specimen.
3. Mix the Rose Bengal Brucella antigen gently but thoroughly. Using the dropper provided, deliver one drop (30pl) of the reagent to each serum sample.
4. Using a clean mixing stick for each specimen, mix the serum and the reagent and spread over the entire circle.
5. Rotate the slide for 4 minutes.
6. Observe under a bright light source for the presence of agglutination.

RESULTS

POSITIVE: A positive result is indicated by agglutination (clumping) of the bacterial suspension.

NEGATIVE: A negative result is indicated by the absence of agglutination.

QUALITY CONTROL

It is recommended that a Brucella positive and a Brucella negative control be tested along with the patient serum for quality control purposes. Use CENOGENICS' BRUCELLA POSITIVE CONTROL and BRUCELLA NEGATIVE CONTROL in place of patient sample and perform test as described above.

LIMITATIONS OF THE PROCEDURE

1 . Agglutinins are not always produced in bacterial infections.
2. Cross reactions may occur in certain pathologies. For instance, Tularemia infections may produce agglutinins to Brucella antigens.
3. Vaccinations may produce cross reacting antibodies.

EXPECTED VALUES

Agglutinins are produced slowly during the acute phase of infection and continue tc form during the convalescent phase of infection. The titer of the concentration of antibody rises considerably between acute infection and convalescence. Therefore, a rise in titer between serum collected during-the acute, or febrile, stage of infection and serum collected during the convalescent stage can be of diagnostic significance.

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