IVD

Blood Culture Bottle (Bi-state/Anaerobic)

Catalog No. M0208/M0209

20 tests

INTENDED USE

This is a qualitative test for the detection of microorganisms in body fluids like blood, ascites, cerebrospinal fluid, etc, offering isolated strains to carry out susceptibility tests.

INTRODUCTION

Blood culture is one of the most important and critical procedures performed in the microbiology laboratory. Since blood is normally sterile, the isolation and identification of an organism has great diagnostic significance. Blood culture is of great importance in diagnosing such conditions as endocarditis, typhoid fever, pneumonia and other diseases characterized by bacteremia.

The growth of microorganisms in a blood culture may be delayed or prevented if an anticoagulant is not used in the culture medium since the organisms may become trapped in the fibrin clot. However, some anticoagulants may be toxic for certain pathogens. In addition, many blood samples contain residual antibiotics, antibodies, ß-lysin and phagocytes which are natural bacterial inhibitors and greatly reduce chances of obtaining a positive culture. These obstacles may be overcome by the use of sodium polyanetholsulfonate (SPS), a nontoxic anticoagulant which enables bacterial growth by counteracting or absorbing those natural bacterial inhibitors in blood. Since SPS inhibits the activity of streptomycin, polymyxin B, kanamycin and gentamicin, therapy with these antibiotics should not interfere with microbial growth in blood cultures containing this anticoagulant.

PRINCIPLE OF THE TEST

All AUTOBIO Blood Culture media will support the growth of a wide variety of clinically important pathogenic microorganisms, including fastidious organisms. There are hemin (x factor) and nicotinamide adenine dinucleotide (v factor) which can sustain *Haemophilus*, *Actinobacillus* and *Cardiobacterium* growing, pyridoxine HCl which is absolutely vital to *Streptococcus* depending on Vitamin B6, SPS which can counteract antimicrobial activity of residual antibiotics and immunity factors. Bi-state system can form a grad of O_2 concentrations in favor of the growth of microorganisms demanding different O_2 concentrations. Colonies obtained from agar state may be directly used to carry out susceptibility experiments and strains identification.

MATERIALS PROVIDED

1. Bi-state Blood Culture Bottle (20 bottles)

or

2. Anaerobic Blood Culture Bottle (20 bottles)

MATERIALS REQUIRED BUT NOT PROVIDED

Incubator（35 – 37℃）

STORAGE OF TEST KIT AND INSTRUMENTATION

This kit should be stored at 4 – 25℃ and avoid exposure to sunlight. The test kit may be used throughout the expiration date (18 months from the date of manufacture). Refer to the package label for the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Samples should be obtained prior to initiating antibiotic therapy. If this is not possible, blood should be drawn immediately before administering the next dose. Samples should also be obtained before meals, since hyperlipemia may obscure visible evidence of bacterium growth in the liquid medium. Bacteremia is intermittent and may precede episodes of fever and chills by about one hour. Blood, ascites and cerebrospinal fluid could be injected into the culture bottle after being collected with aseptic operations.

PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use only.
2. This product has been granted a new type state utility patent in P.R. China, patent number 200420075397.2.
3. Do not use this blood culture bottle if contaminated or broken.
4. Blood anticoagulant has already been applied in the culture bottle, so do not add more.
5. In order to detect septicemia with sufficient accuracy, it may be necessary to carry out one to three blood cultures at designated time intervals, depending on the clinical situations.
6. It is recommended that the collection of blood cultures should be performed at intervals, with samples being obtained at the first sign of fever.
7. The used specimens and its culturing wastes should be treated as potentially contagious material, and be disposed of according to the laboratory operational requirement.

ASSAY PROCEDURE

1. Check if the bottle is contaminated or broken.
2. Prepare and label the appropriate blood culture bottle.
3. Do not unscrew cap. Remove the plastic top of the screw cap on the blood culture bottle.
4. Disinfect the visible part of the rubber plug with iodine or ethyl alcohol (70%) and allow drying.
5. Obtain approximately 3 – 5 ml adult patients' blood per bottle with a needle and syringe or 1 – 3 ml infant patients' blood.
6. Transfer the blood immediately into the culture bottle under aseptic conditions, then disinfect the rubber plug again and replace the plastic top.
7. After the inoculation, lean the bottle several times, and incubate it erectly at 35 – 37℃.
8. When the specimen needs to be inoculated into both Bi-state Blood Culture Bottle and Anaerobic Blood Culture Bottle, the anaerobic bottle must be inoculated before the bi-state one.

INTERPRETATION OF RESULTS

1. Positive results should be reported after incubating the bottle for 24h if such phenomena as broth being turbid, blood corpuscles hemolysis, air bubbles appearing or colonies growing on agar state. Susceptibility experiments and strain identification should be carried out on positive samples.
2. Soak agar state into broth everyday and keep on incubating the bottle erectly if those phenomena do not occur, until the 7th day.
3. If the abovementioned phenomena still do not occur after 7 days of culturing, a negative result could be reported.

LIMITATIONS

Some pathogenic bacteria, especially *Haemophilus influenza* and *Neisseria gonorrhoeae* may have already grown in Bi-state Blood Culture Bottle but do not appear so. In this case, the physician should pick some of the culture broth each day and streak on a chocolate blood agar plate, then place into a 3 – 5% CO_2 incubator calibrated at 35 – 37℃ (blind passage), until the 7th day.

SYMBOLS

	**BATCH CODE**
	**USE BY**
	**MANUFACTURER**

	**CONTAINS SUFFICIENT FOR <n> TESTS**
	***IN VITRO* DIAGNOSTIC MEDICAL DEVICE**
	**TEMPERATURE LIMITATION**
	**CATALOGUE NUMBER**
	**CONSULT INSTRUCTIONS FOR USE**

REFERENCES

1. Tang X, Zhang W and Zhang Z, et. al. 1995. The Identification of Polymorphism as One of the Phenotypes of *Neisseria gonorrhoeae* with a Molecular Biology Method. Chinese Journal of Microecology. **9**: 39 – 41.
2. Yin X, Jiang P, Deng Y, et. al. 2004. The Separation and Identification of *Haemophilus parasuis*. Animal Husbandry & Veterinary Medicine. **36**: 6 – 8.

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