

Aerobic Blood Culture Bottle Instruction

【Product Name】 Aerobic blood culture bottle (30 mL/vial)

【Package】 40 vials/box

【Model】 I-1

【Intended use】

- Used in auto blood culture detection system produced by Zhuhai DL Biotech Co., LTD.
- Used for in vitro diagnosis in clinical laboratory
- For qualitative detection of microbes in human blood or other body fluids under normal sterile conditions
- One time use.

【Detection principles】

This culture bottle contains culture media for microbial and sensors. When the microbial rapidly grown, producing metabolic gas CO₂ and monitored by sensors. According to colorimetry, auto blood culture detection system reports the results of the bottles by detecting sensors.

【Components】

1. Blood culture bottle 40 vials
2. Instruction 1 piece

The main components of culture media(g/L): Columbia broth powder 35g, peptone 10g, potassium dihydrogen phosphate 1.5g, glucose 5g, mannitol 2g, sodium citrate 3g, resin 4g, SPS 0.2g.

【Sample Collection】

- Aseptic technique is necessary.
- Aseptic venipuncture collected blood, urine and cerebrospinal fluid specimens,
- Disinfection of specimen collection site is a must.

【Detection method】

Aseptic technique is necessary in this detection, avoiding of contamination.

- Collect 10 ml of blood or other body fluid with a sterile blood collection tube. Inject it into the culture bottle.
- Insert the inoculated bottle into the auto blood culture detection system, and incubate the microbial.
- The system automatically reports the results and alarms. Negative culture should be incubated for 5 days.

【Result explanation】

If the door indicator flash red light, it reports positive cultures. If no light or sound, it's negative.

【Attention】

- Please don't use it if it's expired.
- Please read the instruction before using it. If it appears turbidity, sedimentation, discoloration in the bottles, stop using.
- Please pay special attention to specimen collection, avoiding false positive caused by bacterial contamination.
- Please pay special attention to bottle disinfection, avoiding false positive caused by bacterial contamination.
- A set of specimens means 3~10 ml of blood or other body fluid for anaerobic blood culture bottle and aerobic blood culture bottle respectively.
- The adult patient who is suspected infected acute primary bacteremia, fungal bacteremia, meningitis, osteomyelitis, arthritis or pneumonia should be immediately collected two or three specimens for blood culture. And culture it at once
- The pediatric patient who has a fever of unknown pathogens, like negative abscess, typhoid fever and heat waves should be immediately collected 2 or 3 sets of specimens from different parts of body, when he starts fevering. After 24 to 36 hours, collect more than 2 sets of specimens before patient temperature gets high(usually in the afternoon).

- It should change the blood culture method when patient is suspected infected bacteremia or fungal bacteremia and its culture reports negative, in order to detect rare or fastidious microbial.
- The adult patient who has infective endocarditic, acute endocarditic should be collected 3 sets of specimens within 2 hrs. If his culture keeps negative, collect 3 more sets of specimens. If the patient ever received antibiotic therapy before going to the hospital within 2 weeks, he should be collected 2 sets of specimens per day on three consecutive days.
- This product is used for IVD only and only for one time. It should be abandoned if damaged or air-leakage of the bottle.
- Must keep operators from infection by certain safety measurement. Must deal with waste as source of infection;

【Key performance Indicators】

- Accuracy rate: The accuracy rate of test results of inoculated QC strains & non-inoculated QC strains is 100%.
- Repeatability: The repeatability of test results of inoculated QC strains & non-inoculated QC strains is 100%.
- Within-run imprecision and Analysis imprecision between batches: Each has no difference.

【Boundedness】

- Accuracy of test results depends on the specimen collection and the operation of blood culture.
- Positive result only indicates the presence of microbial in blood or other body fluids, but does not identify the kind of bacteria.

【Reference】

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2. Centers for disease control Increase in national hospital discharge survey rates for septicemia-United states,1979-1987.MMWR. 1990;39:31-34.
3. Aronson MD,Bor DH. Blood cultures.*Annals Int Med.*1987;106:246-253.
4. Bryan CS ,*Clinical implications of positive blood cultures Clin microbial Rev* 1989;2:329-353.
5. Washington JA II,*Ilstrup DM.blood cutures:issues and controversies.Rev Infect Dis* 1986;8:792-802.
6. Weinstein MP,Murphy JR,Reller LB,Lichenstein KA.*The clinical significance of positive cultures:a comprehensive of 500 episodes of bacteremia and fungemia in adults.I.Laboratory and epidemiologic observations.Rev Infect Dis* 1983;5:35-53.
7. Ilstrup DM.*Statistical methods employed in the study of blood culture media.In:Washington JA 11.ed.The detection of septicemia.West palm Beach:CRC Press* 1978;31-39.
8. Arkin CF,Wwchtel MS.*How many patients are necessary to assess test performance?JAMA* 1990;263:275-278.

【Storage & Validity】

Must be stored in 15-30°C. Valid within 12 months. Should be used soon after opening the box.

REF 2610001011

【Manufacturing Enterprise】

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INDEX OF SYMBOLS

Symbol	Symbol Meaning
	Catalogue number
	In Vitro Diagnostic Medical Device
	Manufacturer
	Production date
	Temperature limitation
	Expiry date
	Batch code
	Consult Instructions for Use