Technical Data

TSB - Tryptone Soya Broth Supplemented with 0.05% SPS

LQ011A

Intended Use:

Recommended as a qualitative test for detection of microorganisms in blood. *Sterile, in glass bottles*.

Composition**

Ingredients	g/ L
Tryptone	17.000
Soya peptone	3.000
Sodium chloride	5.000
Dextrose (Glucose)	2.500
Dipotassium hydrogen phosphate	2.500
Sodium polyanethol sulphonate (SPS)	0.500
Final pH (at 25°C)	7.3±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Label the ready to use blood culture bottle. Do not unscrew cap. remove the top of the screw cap. Disinfect the part of the rubber stopper which is now exposed. Draw patient's blood with the sterile or disposable needle and syringe as explained in specimen collection and disposable column. Transfer the blood sample immediately into the culture bottle by puncturing the rubber stopper with the needle and injecting the blood. Venting: Use sterile venting needle (LA038). Keep the bottle in an upright position preferably in a biological safety cabinet, place an alcohol swab over the rubber stopper and insert the venting needle with filter through it. Insertion and withdrawal of the needle should be done in a straight line. discard the needle and mix the contents by gently inverting the bottle 2-3 times. Do Not vent the bottle for anaerobic cultures. Incubate at 35±2°C for 18-24 hours and further for seven days.

Principle And Interpretation

Soyabean Casein Digest Medium is recommended by various pharmacopeias as a sterility testing and as a microbial limit testing medium (1,2). This medium is a highly nutritious medium used for cultivation of a wide variety of organisms (3,4). Bacteremia is a serious and often life-threatening clinical condition. An important diagnostic tool for this condition is to analyze a blood specimen for the growth of bacteria on selected growth media. Such media often contain SPS as an anticoagulant and as an inhibitor of the bacteriostatic and bactericidal effects of blood cells and plasma factors (5,6).

The combination of tryptone and soya peptone makes the medium nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Dextrose (Glucose) and dipotassium hydrogen phosphate serve as the carbohydrate source and the buffer, respectively in the medium. Sodium chloride maintains the osmotic balance of the medium. Sodium Polyanethole Sulphonate (SPS) which is an anticoagulant in culture bottles promotes optimal recovery of organisms from blood (7). It acts to inhibit phagocytosis and to neutralize the antibacterial activity of fresh blood components (8,9).

Type of specimen

Clinical sample: Blood

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (10,11).

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic use only. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.
2. Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's unique requirement.
3. Recommended for Adult use, not for paediatric use

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Sterile clear Tryptone Soya Broth supplemented w/ 0.05% SPS in glass bottle.

Colour

Light yellow coloured clear solution

Quantity of Medium

70 ml of medium in glass bottle, (For Adult use)

pH

7.10-7.50

Sterility Check

Passes release criteria.

Cultural response

Cultural characteristics observed after an incubation at at 35-37°C for <= 3 days

Organism	Inoculum (CFU)	Growth
Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*)	50 -100	luxuriant
Escherichia coli ATCC 25922 (00013*)	50 -100	luxuriant
Pseudomonas aeruginosa ATCC 27853 (00025*) ^	50 -100	luxuriant
Bacillus spizizenii ATCC 6633 (00003*)	50 -100	luxuriant
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant
Salmonella Abony NCTC 6017 (00029*)	50 -100	luxuriant
Streptococcus pneumoniae ATCC 6305	50 -100	luxuriant
Streptococcus pyogenes ATCC 19615	50 -100	luxuriant
Candida albicans ATCC 10231 (00054*)	50 -100	luxuriant
# *Aspergillus brasiliensis* ATCC 16404 (00053*)	50 -100	luxuriant

Key : (*) Corresponding WDCM numbers, (#) Formerly known as *Aspergillus niger*
^ Formerly known as *Bacillus subtilis* subsp. *spizizenii*

Storage and Shelf Life

On receipt store between 15-30°C. Use before expiry date on the label. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (10,11).

References

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IVD *In vitro* diagnostic medical device

30°C 15°C Storage temperature

EC REP CEpartner4U, Esdoornlaan 13,
3951DB Maarn, NL
www.cepartner4u.eu

CE Marking

Do not use if package is damaged

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