REF 42 100

11772 **E** - en - 2008/10

Trypcase Soy Broth (TSB-T)

IVD

Culture of non-fastidious micro-organisms

SUMMARY AND EXPLANATION

Trypcase Soy broth is a culture medium for the growth of most non-fastidious micro-organisms (bacteria and fungi) (1, 2).
It is used, in the pharmaceutical industry, for the microbiological control of non-sterile products. This medium complies with the performance requirements in the harmonized chapters of the European, United States, and Japanese Pharmacopoeia (3, 4, 5).

PRINCIPLE

This broth contains a mixture of peptones enabling the growth of most non-fastidious microorganisms.

CONTENT OF THE KIT

	Ready-to-use medium
REF 42 100	20 x 9 ml tubes

COMPOSITION

Theoretical formula

This medium can be adjusted and/or supplemented according to the performance criteria required:

Casein peptone (bovine)	17 g
Soy peptone	3 g
Sodium chloride	5 g
Dipotassium phosphate	2.5 g
Dextrose	2.5 g
Purified water	1 l

pH 7.3

MATERIAL REQUIRED BUT NOT PROVIDED

- Controlled atmosphere generators.
- Jars.
- Bacteriology incubator.
  Or
- Thermoregulated chambers with a controlled atmosphere.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use and microbiological control.
- For professional use only.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (do not ingest or inhale).
- All specimens, microbial cultures and inoculated products should be considered infectious and handled appropriately. Aseptic technique and usual precautions for handling the bacterial group studied should be observed throughout this procedure. Refer to "CLSI® M29-A, *Protection of Laboratory Workers from Occupationally Acquired Infections*; *Approved Guideline* - Current Revision". For additional handling precautions, refer to "Biosafety in Microbiological and Biomedical Laboratories, CDC/NIH, Latest Edition", or to the regulations currently in use in each country.
- Culture media should not be used as manufacturing material or components.
- Do not use reagents after the expiry date.
- Do not use tubes which show signs of contamination.
- Before use, check that the tube cap is intact.
- Microscopic elements, possibly coming from dead micro-organisms, may be observed in the broth, but this does not alter the performance of the medium.
- The performance data presented were obtained using the procedure indicated in this package insert. Any change or modification in the procedure may affect the results.
- The outside of the tubes is not sterile. For sterility testing, take all necessary precautions during inoculation and do not place the tubes in an isolator.

STORAGE CONDITIONS

- **The tubes can be stored in their box at 2-25°C until the expiry date.**

SPECIMENS

For use in medical bacteriology:

This medium can be used to subculture bacterial or fungal strains.

For use in industrial bacteriology:

Follow the recommendations in the harmonized chapters of the Pharmacopoeia to perform specimen preparation.

INSTRUCTIONS FOR USE

For use in medical bacteriology:

1. Inoculate the strain to be subcultured directly into the tube.
2. Place the tube in a suitable atmosphere, if necessary using a controlled atmosphere generator.
3. Incubate at 37°C, with the cap loosened. The user is responsible for choosing the appropriate temperature for the intended use, in accordance with current standards.
   The cultures are generally examined after 24-48 hours of incubation. Incubation time varies according to the type of specimen and the micro-organisms being tested for.

For use in industrial bacteriology:

<u>For the microbiological control of non-sterile products:</u>
Refer to the method described in the harmonized chapters of the Pharmacopoeia.
For the detection of *E. coli, Salmonella, P. aeruginosa* and *S. aureus*, the optimum incubation temperature is 35°C.

<u>For sterility testing:</u>

- when the specimen cannot be filtered and only a small quantity is available for testing, this broth can be used for direct inoculation and incubated for 14 days at 20-25°C.
- when the specimen can be filtered, it is recommended to use the bottles ref. 44011, adapted to membrane sterility testing.

READING AND INTERPRETATION

For use in medical bacteriology:

- After incubation, observe the microbial growth, associated with turbidity of the broth.
- Subculture the broth on an appropriate pre-plated medium.

For use in industrial bacteriology:

For the microbiological control of non-sterile products:

Follow the procedure in the harmonized chapters of the Pharmacopoeia.

For sterility testing:
Examine the broths several times both during incubation and at the end of incubation in order to detect microbial proliferation. If a specimen causes turbidity in the medium immediately after inoculation, systematically subculture at the end of incubation.

QUALITY CONTROL

For use in medical bacteriology:

Protocol:
The nutrient capacity of the medium can be tested using the following strain:
Staphylococcus aureus ATCC® 25923

Range of expected results:
At 33-37°C, the tested strain should grow within 24 hours.

Note:
It is the responsibility of the user to perform Quality Control taking into consideration the intended use of the medium, and in accordance with any local applicable regulations (frequency, number of strains, incubation temperature, etc.).

For use in industrial bacteriology:

- The control complies with the recommendations in the harmonized chapters of the Pharmacopoeia.

LIMITATIONS OF THE METHOD

- Growth depends on the requirements of each individual micro-organism. It is therefore possible that certain strains which have specific requirements (substrate, temperature, incubation conditions, etc.) may not develop.
- The pH of the medium may decrease during the product's shelf-life to as low as 7.0. It has been verified that this decrease in pH does not modify performance.

PERFORMANCE

Performance was evaluated at 37°C using 18 bacterial strains (*Neisseria, Brucella*, streptococci, *Listeria,* staphylococci and Gram-negative bacilli) and 1 yeast (*Candida*).

Results:

All the strains tested grew within 24 hours, with the exception of the *Neisseria* and *Brucella* strains which grew within 48 hours.

WASTE DISPOSAL

Dispose of used or unused reagents as well as any other contaminated disposable material following procedures for infectious or potentially infectious products.
It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

LITERATURE REFERENCES

1. GRETLER A.C., MUCCIOLO P., EVANS J.B. et al. - Vitamin nutrition of the Staphylococci with special reference to their biotin requirements - *J. Bacteriol.*, 1955, vol. 70, p. 44-49.
2. MURRAY P.R., BARON E.J., PFALLER M.A. et al. - 1995 – *Manual of clinical microbiology, 6th ed*. - American Society for Microbiology, Washington, D.C. – ISBN 1-55581-086-1.
3. European Pharmacopoeia EP 5.
4. United States Pharmacopoeia USP 29.
5. Japanese Pharmacopoeia JP 15.

INDEX OF SYMBOLS

Symbol	Meaning
REF	GB : Catalogue number US : Catalog number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests

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