INSTRUCTIONS FOR USE

SABOURAUD BROTH

Ready-to-use tubes

Sabouraud Broth – from left: un-inoculated tube and growth of *Aspergillus brasiliensis*

1 - INTENDED USE

In vitro diagnostic device.
Liquid medium for the cultivation of yeasts and moulds.

2 - COMPOSITION -TYPICAL FORMULA *

Peptic digest of animal tissue	5 g
Pancreatic digest of casein	5 g
Glucose	20 g
Purified water	1000 mL

*the formula may be adjusted and/or supplemented to meet the required performances criteria.

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

Sabouraud Broth, also known as Sabouraud Dextrose Broth, is a modification proposed by Sabouraud to the Sabouraud Dextrose Agar medium, without agar and with half-concentration of glucose.[1,2]
Sabouraud Broth is a liquid medium intended for the cultivation of yeasts and moulds.[3] The medium is recommended for growth promotion test, for the preparation of the sample and its pre-enrichment in the procedure for the detection of *Candida albicans* in non-sterile products with EP harmonized method.[4] Sabouraud Broth complies with the quality specifications reported in the harmonized method.
Pancreatic digest of casein and peptic digest of animal tissue provide nitrogen, carbon and trace elements for microbial growth. The low pH is favourable for the growth of fungi and aciduric microorganisms. Glucose, at high concentration is a carbon and energy source.

4 - PHYSICAL CHARACTERISTICS

Medium appearance	yellow, limpid
Final pH at 20-25°C	5.6 ± 0.2

5 - MATERIALS PROVIDED - PACKAGING

Product	Type	REF	Pack
Sabouraud Broth	Ready-to-use tubes	552000	20 x 9 mL glass tubes, 17x125 mm, flat bottom, aluminium screw-cap. Packaging: cardboard box

6 - MATERIALS REQUIRED BUT NOT PROVIDED

Sterile loops and swabs, incubator and laboratory equipment as required, ancillary culture media and reagents for the identification of the colonies.

7 - SPECIMENS

Sabouraud Broth is primarily intended for the cultivation of yeasts and moulds isolated on plated media. It may be used for the inoculation of clinical samples such as skin scrapings for the cultivation of pathogenic and opportunistic fungi. Collect clinical specimens before antimicrobial therapy where possible. Good laboratory practices for collection, transport and storage of the clinical specimens should be applied. In pharmaceutical microbiology, the samples consist of the pharmaceutical products on which detect *Candida albicans*. Refer to the European Pharmacopoeia for sample collection and transport procedures.

8 - TEST PROCEDURE

Allow the tubes to come to room temperature.
Inoculate each test strain or specimen into duplicate tubes. Incubate one tube at 22-25°C and the second at 35°C for 2-7 days.
The incubation conditions may vary according to the type of expected microorganisms and can be extended up to 30 days.
The user is responsible for choosing the appropriate incubation time and temperature depending on the processed specimen or inoculated strain, the requirements of organisms to be recovered or cultivated and the local applicable protocols.

9 - READING AND INTERPRETATION

After incubation, the presence of microbial growth is evidenced by the presence of turbidity compared to an un-inoculated control. The characteristic of the growth is closely related to the type or types of cultivated microorganisms.

10 - USER QUALITY CONTROL

All manufactured lots of the product are released for sale after the Quality Control has been performed to check the compliance with the specifications. However, the end user can perform its own Quality Control in accordance with the local applicable regulations, in compliance with accreditation requirements and the experience of the Laboratory. Here below are listed some test strains useful for the quality control.

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CONTROL STRAINS		INCUBATION T°/ T / ATM	EXPECTED RESULTS
C.albicans	ATCC 10231	20-25°C / up to 72 h / A	growth
A.brasiliensis	ATCC 16404	20-25°C / up to 72 h / A	growth
T.rubrum	ATCC 28188	20-25°C / up to 72 h / A	growth

For quality control in the pharmaceutical field refer to the current edition of European Pharmacopoeia.
A: aerobic incubation; ATCC is a trademark of American Type Culture Collection

11 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of ready to use tubes of Sabouraud Broth and of the raw material used for the production of prepared tubes (dehydrated Sabouraud Broth REF 402000) is tested for productivity by comparing the results with a previously approved Reference Batch.
Productivity is tested by dilution to extinction method, by inoculating 1 mL of appropriate decimal dilutions of organisms in test tubes, incubating at 20-25°C for up to 72 hours and recording the highest dilution showing growth in Reference Batch (Gr_{RB}) and in Test Batch (Gr_{TB}). Productivity is tested with the following target strains: *C.albicans* ATCC 18804*, A.brasiliensis* ATCC 16404*, P.chrysogenum* ATCC 10106, *T.rubrum* ATCC 28188, *M.canis* ATCC 36299, *L.casei* ATCC 393. Productivity is also tested with *C.albicans* ATCC 10231 incubating at 30-35°C for 24 hours according to EP. The productivity index Gr_{RB}-Gr_{TB} for each test strain shall be ≤ 1.

12 - LIMITATIONS OF THE METHOD

- Since Sabouraud Broth is a general-purpose medium with very poor selective properties, bacterial strains will also grow.
- It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on isolates, from pure culture, for complete identification. If relevant, perform antimicrobial susceptibility testing.
- This culture medium is intended as an aid in the diagnosis of infectious diseases; the interpretation of the results must be made considering the patient's clinical history, the origin of the sample and the results of other diagnostic tests.

13 - PRECAUTIONS AND WARNINGS

- This product is a qualitative *in vitro* diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- This product is not classified as dangerous according to current European legislation.
- This culture medium contains raw materials of animal origin. The *ante* and *post mortem* controls of the animals and those during the production and distribution cycle of the raw materials, cannot completely guarantee that these products do not contain any transmissible pathogen. Therefore, it is recommended that the ready-to-use tubes be treated as potentially infectious, and handled observing the usual specific precautions: do not ingest, inhale, or allow to come into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website www.biolifeitaliana.it, describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as culture medium or microbial agents.
- Each tube is for single use only; do not transfer or subdivide the tube content in other containers.
- Be careful when opening screw cap tubes to prevent injury due to breakage of glass.
- Ready-to-use tubes of are subject to terminal sterilization by autoclaving.
- Sterilize all biohazard waste before disposal. Dispose the unused medium and the tubes inoculated with samples or microbial strains in accordance with current local legislation.
- The Certificates of Analysis and the Safety Data Sheet are available on the website www.biolifeitaliana.it.
- Notify Biolife Italiana Srl (complaint@biolifeitaliana.it) and the relevant Authorities of any serious incident occurring in connection with the use of the *in vitro* diagnostics.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.

14 - STORAGE CONDITIONS AND SHELF LIFE

Upon receipt, store tubes in their original pack at 2-8°C away from direct light. If properly stored, the tubes may be used up to the expiration date. Do not use the tubes beyond this date. After opening the box, the tubes can be used up to the expiration date. Opened tubes must be used immediately. Before use, check the integrity of the screw cap. Do not use tubes with signs of deterioration (e.g. microbial contamination, atypical colour, precipitate).

15 – REFERENCES

1. Espinel-Ingroff A. History of medical mycology in the United States. Clin Microbiol Rev 1966;9:235-272
2. Sabouraud R. Contribution a l'étude de la trichophytie humaine. Etude clinique, microscopique et bacterioloqique sur la pluralité des trichophytons de l'homme. Ann Dermatol Syphil1892; 3:1061-1087.
3. Atlas R, Parks L. Media Handbook of Microbiological Media 2nd ed CRC Press, 1997
4. European Pharmacopoeia, current edition

TABLE OF APPLICABLE SYMBOLS

REF or **REF** Catalogue number	**LOT** Batch code	**IVD** *In vitro* Diagnostic Medical Device	Manufacturer	Do not reuse	Recyclable pack This side up
Temperature limitation	Content sufficient for <n> tests	Consult Instructions for Use	Use by	Keep away from direct light	Fragile

REVISION HISTORY

Version	Description of changes	Date
Instructions for Use (IFU) - Revision 1	Updated layout and content in compliance with IVDR 2017/746	2021/06
Revision 2	Removal of obsolete classification	2023/04

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.

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