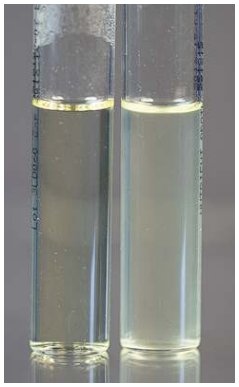
INSTRUCTIONS FOR USE

NUTRIENT BROTH

Ready-to-use tubes



Nutrient Broth – from the left: un-inoculated tube, growth of *E.faecalis*

1 - INTENDED USE

In vitro diagnostic device. General purpose liquid medium for the cultivation of non-fastidious microorganisms isolated from clinical and non-clinical specimens.

2 - COMPOSITION -TYPICAL FORMULA *

Beef extract	3.0 g
Peptone	5.0 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

Nutrient Broth is a medium suitable for the cultivation of non-fastidious microorganisms isolated from clinical and non-clinical specimens. It was included in several Standards for the examination of water, food, dairy products[1-3]; it is not a recommended bacteriological medium in later editions of these publications.
Nutrient Broth is one of several non-selective media useful in routine cultivation of microorganisms. It can be used for the sub-culture of colonies grown on other media to be tested with bacteriological and serological assays.
The peptone and meat extract provide carbon, nitrogen, vitamins and minerals sufficient for the growth of most non-fastidious microorganisms (*Enterobacteriaceae*, enterococci, staphylococci, etc.).

4 - PHYSICAL CHARACTERISTICS

Medium appearance	very pale yellow, limpid
Final pH at 20-25°C	6.8 ± 0.2

5 - MATERIALS PROVIDED - PACKAGING

Product	Type	REF	Pack
Nutrient Broth	Ready-to-use tubes	551815	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 isolation and the identification of the colonies.

7 - SPECIMENS

Nutrient Broth can be used for the sub-culture of colonies grown on primary isolation media. It is not suitable for the direct inoculation of clinical specimens.

8 - TEST PROCEDURE

With a bacteriological needle or loop inoculate the liquid medium in the test tube with a colony grown on a plating medium.
Routinely, incubate at 35-37°C in aerobic conditions for 18-24 hours.
The user is responsible for choosing the appropriate incubation time, temperature and atmosphere depending on the processed specimen, the requirements of organisms to be recovered and the local applicable protocols.

9 - READING AND INTERPRETATION

After incubation, growth of organisms is indicated by turbidity of inoculated tubes.

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.

CONTROL STRAINS	INCUBATION T°/ T / ATM	EXPECTED RESULTS
E.coli ATCC 25922	35-37°C / 18-24h / A	growth
E.faecalis ATCC 19433	35-37°C / 18-24h / A	growth

A: aerobic incubation; ATCC is a trademark of American Type Culture Collection

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11 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of ready-to-use tubes of Nutrient Broth and of the raw material used for the production of prepared tubes (dehydrated Nutrient Broth REF 401815) 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 35-37°C for 18-24 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: *E.coli* ATCC 25922, *E.aerogenes* ATCC 13048, *K.pneumoniae* ATCC 27736, *S.aureus* ATCC 25923, *E.faecalis* ATCC 19433, *S.epidermidis* ATCC 12228. The productivity index Gr_{RB}-Gr_{TB} for each test strain shall be ≤ 1.

12 - LIMITATIONS OF THE METHOD

- 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. American Public Health Association. Standard Methods for the Examination of Water and Wastewater. 1980, 15th Ed. APHA Inc. Washington DC.
2. American Public Health Association. Standard Methods for the Examination of Dairy Products.1978,14th Ed. APHA Inc. Washington DC.
3. American Public Health Association. Compendium of Methods for the Microbiological Examination of Foods. 2001, 4th Ed.

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 2017/74	2021/04
Revision 2	Removal of obsolete classification	2023/04

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