

INSTRUCTIONS FOR USE

BRAIN HEART INFUSION BROTH

Ready-to-use tubes

 Brain Heart Infusion Broth:
 from left: un-inoculated tube, growth of *S. aureus*
1 - INTENDED USE

In vitro diagnostic device. General purpose medium for the cultivation of fastidious and non-fastidious microorganisms, including aerobic and anaerobic bacteria and fungi from a variety of clinical and non-clinical specimens.

2 - COMPOSITION - TYPICAL FORMULA *

Dehydrated brain infusion	12.5 g
Dehydrated heart infusion	5.0 g
Enzymatic digest of animal tissues	10.0 g
Glucose	2.0 g
Sodium chloride	5.0 g
Disodium hydrogen phosphate	2.5 g

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

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

Brain Heart Infusion (BHI) Broth is based on the formula proposed in 1919 by Edward Rosenow¹ and later modified in 1923 by Russell Haden². Modern BHI Broth typically uses a dried infusions from brain and heart, rather than calf brain tissue, and uses disodium phosphate as a buffer, rather than the calcium carbonate used by Rosenow and Haden.

BHI Broth is a general purpose, nutritionally rich medium for the cultivation and maintenance of a variety of fastidious and non-fastidious microorganisms, including aerobic and anaerobic bacteria, yeasts and moulds, from clinical and non-clinical specimens using suitable incubation temperatures and time³. BHI Broth is used for the preparation of staphylococcal broth culture for performing coagulase test.⁴ BHI Broth can be used to start the culture process for urease test of *H. pylori*.^{5,6}

Brain and heart infusions and peptone are sources of nitrogen, carbon, vitamins and minerals for microbial growth; glucose provides an energy source, sodium chloride maintains osmotic balance, dibasic sodium phosphate is included as a buffer system.

4 - PHYSICAL CHARACTERISTICS

Medium appearance	yellow, limpid
Final pH at 20-25°C	7.4 ± 0.2

5 - MATERIALS PROVIDED - PACKAGING

Product	Type	REF	Pack
Brain Heart Infusion Broth CND: W0104010206, EDMA: 14.01.02.01; RDM: 1513681/R	Ready-to-use tubes	551230	20 x 9 mL glass tubes, 17x125 mm, flat bottom, aluminium screw-cap. Packaging: cardboard box
Brain Heart Infusion Broth CND: W0104010206, EDMA: 14.01.02.01; RDM: 1513681/R	Ready-to-use tubes	521230P	24 x 3 mL glass tubes, 15x45 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

Brain Heart Infusion Broth can be used for the sub-culture of colonies grown on primary isolation media. It can also be inoculated with a variety of clinical and non-clinical samples following the procedures described in the literature.⁶ Good laboratory practices for collection, transport and storage of clinical specimens should be applied. Collect specimens before antimicrobial therapy where possible.

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 or with one or two drops of the specimen, if liquid, using a sterile pipette. Swab specimens may be inserted into broth after inoculation of plated media. 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

The presence of microorganisms is indicated by a varying degree of turbidity, specks and flocculation in the medium. The un-inoculated control remains clear and without turbidity after incubation. The characteristics of growth is closely related to the type or types of microorganisms grown.





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, it is responsibility of the end-user to perform Quality Control testing 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.⁷

CONTROL STRAINS	INCUBATION T° / T / ATM	EXPECTED RESULTS
<i>S.aureus</i> ATCC 25923	35-37°C / 18-24H / A	good growth
<i>E.coli</i> ATCC 25922	35-37°C / 18-24H / A	good growth

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 and the raw materials (dehydrated Brain Heart Infusion Broth REF 401230) (Test Batch: TB), is tested for productivity by comparing the results with a previously approved Reference Batch (RB). Productivity is tested by dilution to extinction method, by inoculating 1 mL of appropriate decimal dilutions of organisms in test tubes and incubating at 30-35°C or at 20-25°C for 18-24 hours or for 24-72 hours and recording the highest dilution showing growth in Reference Batch (G_{RB}) and in Test Batch (G_{TB}). Productivity is tested with the following strains: *S.aureus* ATCC 25923, *S.pyogenes* ATCC 19615, *S.pneumoniae* ATCC 6301, *E.faecalis* ATCC 19433, *E.coli* ATCC 25922, *N.gonorrhoeae* ATCC 19424, *C.albicans* ATCC 18804, *A.brasiliensis* ATCC 9642. The productivity index $G_{RB}-G_{TB}$ for each test strain shall be ≤ 1 .

12 - LIMITATIONS OF THE METHOD

- The nutritional requirements of microorganisms can be different, it is therefore possible that some microbial strains do not grow or grow scantily.
- Sub-cultures onto suitable solid media are necessary for purification of the culture and to perform identification tests.
- Biochemical, immunological, molecular, or mass spectrometry testing should 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 contents in other containers.
- Be careful when opening screw cap tubes to prevent injury due to breakage of glass.
- Ready-to-use tubes are subject to 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.
- 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. Rosenow EC. Studies on elective localization. J Dent Research 1919; 1:205-49.
2. Hayden RL. Elective localization in the eye of bacteria from infected teeth. Arch Int Med 1923; 32:828-49.
3. Atlas R, Snyder J. Reagents, Stains and Media: Bacteriology. In Carrol KC, Pfaller MA et al. editors. Manual of clinical microbiology, 12th ed. Washington, DC: American Society for Microbiology; 2019
4. ISO 6888-1:1999 Microbiology of food and animal feeding stuffs -- Horizontal method for the enumeration of coagulase-positive staphylococci (*Staphylococcus aureus* and other species). Part 1: Technique using Baird-Parker agar medium.
5. Public Health England- UK Standards for microbiology investigations (UK SMI) B55. Investigation of infectious causes of dyspepsia. Issue no: 7; 03.10.2019
6. McElvania E, Singh K. Specimen Collection, Transport and Processing: Bacteriology. In Carrol KC, Pfaller MA et al. editors. Manual of clinical microbiology, 12th ed. Washington, DC: American Society for Microbiology; 2019.
7. CLSI (formerly NCCLS) Quality Control of Commercially Prepared Culture Media. Approved Standard, 3rd edition. M22 A3 vol. 24 n° 19, 2004.





TABLE OF APPLICABLE SYMBOLS

 or  Catalogue number	 Batch code	 <i>In vitro</i> 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 4	Updated layout and content in compliance with IVDR 2017/746	2020/12

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

