



LBM™
BHI Broth

Package insert and How to use guide



Copan Brain Heart Infusion Broth (BHI Broth) – Product Insert & How to Use Guide

INTENDED USE

Copan BHI (Brain Heart Infusion) broth is an enrichment medium that supports fastidious aerobic bacteria growth. Clinical specimens can be inoculated into **Copan BHI broth** and after appropriate incubation, plated on nutritive or selective agar.

SUMMARY

Brain Heart Infusion broth consists in an infusion of brain and beef heart, peptone and carbohydrate dissolved in buffered solution, resulting in enrichment that supports fastidious aerobic bacteria. The Copan BHI is available in 3 ml volume on 12x80 screw cap tube. It can be used with manual method or in automation like WASP. Consult table below for manual or automated codes.

REAGENTS

BHI broth components (per liter):

Components name	g/liter
Brain infusion solids	12.5
Beef heart infusion solids	5.0
Protease peptone	10.0
Glucose	2.0
Sodium chloride	5.0
Disodium phosphate	2.5
Water	1000 ml

STORAGE

This product is ready to use and no further preparation is necessary. The unopened bulk pack or individual kit pack can be stored at 5 - 25°C until used or until the expiration date. Do not overheat. Do not incubate or freeze prior to use. Improper storage will result in loss of efficacy. Do not use after expiration date, which is clearly printed on the outer box.

PRODUCT DETERIORATION

Do not use **Copan BHI broth** if: (1) the product shows visible marks of damage or contamination; (2) there is evidence of leakage; (3) the expiration date has passed; (4) there are other signs of deterioration.(i.e. medium is turbid).

MATERIALS SUPPLIED

Catalog No.	Product Descriptions	Pack Size	Suitable for Automation
474CE	3 ml of BHI broth in 12x80 mm polypropylene screw-cap tube with internal conical shape.	50 units per shelf pack 6X50 units per box	NO
474CE.A	3 ml of BHI broth in 12x80 mm polypropylene screw-cap tube with internal conical shape.	50 units per shelf pack 6X50 units per box	YES

MATERIALS REQUIRED BUT NOT SUPPLIED

Appropriate materials for the cultivation and isolation of bacteria after to laboratory reference manuals for recommended protocols for culture and identification techniques.

INSTRUCTIONS FOR USE SPECIMEN COLLECTION

For the specimen collection procedure refer to the published reference documentation. A correct specimen collection represents the most critical phase for the isolation and identification of the pathogenic organism.

The Copan Eswab system can be used for the specimen collection. Ask Copan for the most correct code to use and refers to the PI of the product for instructions to use.

SPECIMEN PROCESSING IN LABORATORY

PROCEDURE_ MANUAL OPERATION

1. Take the BHI broth tube and unscrew the cap.
2. Inoculate the sample into the opened tube.
 - For liquid samples, a loop or a pipette can be used to transfer the sample into the tube.
 - If a swab sample is available, insert the swab directly into the medium, swirl a few times and remove it.
 - For Eswab Sample, after vortexing the tube for 10sec unscrew the cap and transfer the swab from the ESwab tube to the BHI tube by using sterile forceps; alternatively inoculate the BHI broth with 30µL of Amies inoculated media by a micropipette. Re-cap the ESwab tube
3. Re-cap the tube of BHI broth and vortex it for 5-10 seconds at 2000/2500 rpm in order to mix the tube content
4. Incubate the inoculated BHI broth tubes at 35 ± 2 °C.
5. Examine the BHI broth tube for growth after 18-24 hours and, if negative, re-incubate for additional 24 hours.
6. Aseptically remove the BHI broth and inoculate and plate on nutritive or selective agar or as per laboratory standard procedure.
7. Incubate inoculated BHI broth tubes at 35 ± 2 °C.



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8. Examine the BHI broth tube for growth after 18-24 hours.
9. Aseptically remove aliquots of the BHI broth and inoculate onto appropriate bacteriology selective medium.

PROCEDURE AUTOMATIC OPERATION

The BHI broth is manufactured in a container suitable to be processed by automatic system for planting and streaking (WASP). By using the WASP is possible to inoculate specimens collected by the ESwab system into the broth and to subculture the enriched broth sample.

BROTH INOCULATION BY THE WASP

1. Process the specimen collected in ESwab by a specific broth inoculation protocol by using the 30µL loop. Refer to the WASP User Manual for further information.
2. Examine the BHI broth tube for growth after 18-24 hours and, if negative, re-incubate for additional 24 hours.

SUBCULTURE OF THE ENRICHED BROTH SAMPLE BY THE WASP

1. Process the enriched BHI sample by a specific protocol for the streaking of an appropriate selective medium plate. The use of a 1 or 10µL loop and a multiple quadrant streaking pattern (3-4 Quadrants type) is suggested in order to improve the colonies isolation. It is recommended the laboratory to validate the streaking protocol. Refer to the WASP User Manual for further information.
2. Incubate the plates according to the standard laboratory procedure.

LIMITATIONS

1. It is possible that some fastidious strains with specific requirements, as some Haemophilus species with factor X and/or V, do not grow on this medium.
2. Condition, timing, and volume of specimen collected for culture are significant variables in obtaining reliable culture results. Follow recommended guidelines for specimen collection.
3. Performance testing with Copan BHI broth was conducted using laboratory strains spiked into the BHI broth tube and not using human specimens.
4. Proper specimen collection from the patient is extremely critical for successful isolation and identification of infectious organisms. For specific guidance regarding specimen collection procedures, consult published reference manuals. Specimens should be collected as soon as possible after the clinical onset of disease. Highest bacterial titres are present during the acute illness.

WARNINGS

1. For in vitro diagnostic use.
2. Ⓜ This product is for single use only; reuse may cause a risk of inaccurate results.
3. Not suitable for any other application than intended use.
4. Work under a biological safety cabinet, wear gloves and other protection commensurate with universal precautions when handling clinical specimens.
5. The use of this product in association with any diagnostic assay or with any diagnostic instrumentation should be validated by the user before using.
6. Do not use if the product is visibly damaged.
7. Do not ingest the medium.
8. The manufacturer cannot be held responsible for any inappropriate or unqualified use of the product.
9. All specimens considered infectious and must be handled with appropriate precautions.
10. Copan BHI broth is for in-vitro diagnostics use only and is in no way intended for curative or prophylactic purposes.
11. Observe approved biohazard precautions and aseptic techniques. Product to be used only by adequately trained and qualified personnel.
12. Directions should be read and followed carefully.

WASTE DISPOSAL

Unused reagents may be considered as non hazardous waste and disposed of accordingly.

Dispose of used reagents as well as any other contaminated disposable materials 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.

RESULTS:

Results obtained depend on adequate specimen collection and timely transport and processing in the laboratory.

PERFORMANCE CHARACTERISTICS AND QUALITY CONTROL PROCEDURE:

Procedure for testing:

- Starting from a fresh culture prepare 0.5 Mc Farland suspension of each organism in PBS.
- From the 0.5 McF suspension prepare appropriate dilution to contain from 300 to 3000 CFU/100 ul
- Using a micropipette inoculate 30 ul of each prepared bacteria suspension into a tube of BHI broth
- Vortex inoculated BHI tube for 10 seconds to mix.
- Plate 30 ul of inoculate BHI broth onto TSA plates and incubate at 35+/-2°C for 18-24 hours as zero time baseline colony count.
- Incubate the inoculate BHI broth tube at 35+/-2°C for 18-24 hours
- After 18-24 hours take-out from the incubator the BHI tube and vortex for 10 seconds.
- Plate 30 ul of the inoculated BHI broth onto TSA plate.
- Incubate the inoculated TSA at 35+/-2°C for 18-24 hours
- NOTE: the BHI broth tube should appear cloudy.
- Read and record colony count.

ACCEPTABILITY LIMITS: GROWTH.



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PERFORMANCE TEST RESULTS:

STRAIN [¶]	ZERO TIME COUNT; CFU/PLATE	CFU COUNT AFTER 18-24 HOURS at 35°C±2°C; CFU/PLATE
Escherichia coli ATCC 25922	158	CONFLUENT GROWTH
Staphylococcus aureus ATCC 25923	126	CONFLUENT GROWTH
Streptococcus pneumoniae ATCC 6305	162	CONFLUENT GROWTH

[¶] Performance testing with Copan BHI broth was conducted using laboratory strains. Performance testing was not conducted using human specimens. The product BHI broth is in compliance with CLSI-M22-A3.

ITALIANO

Brodo Brain Heart Infusion della Copan (brodo BHI) – Foglio illustrativo del prodotto e Guida per l'uso

USO PREVISTO

Il brodo BHI (Brain Heart Infusion) della Copan è un terreno di arricchimento che supporta la crescita dei batteri aerobici fastidiosi. I campioni clinici possono essere inoculati nel brodo Copan BHI e, dopo un'opportuna incubazione, coltivati su agar nutritivo o selettivo.

RIASSUNTO

Il brodo Brain Heart Infusion è costituito da un'infusione di cervello e cuore di bovino, peptone e carboidrati dissolti in una soluzione tamponata, dando come risultato un arricchimento che favorisce i batteri aerobici fastidiosi.

Il BHI della Copan è disponibile con un volume da 3 ml in tubi con tappo a vite da 12x80. Può essere usato con il metodo manuale, o con sistemi automatici come lo WASP. Consultare la tabella per i codici manuali o automatizzati.

REAGENTI

Componenti del brodo BHI (per litro):

Nome dei componenti	g/litro
Infusione di cervello	12.5
infusione di cuore di bovino	5.0
Peptone proteasi	10.0
Glucosio	2.0
Cloruro di sodio	5.0
Fosfato disodico	2.5
Acqua	1000 ml

IMMAGAZZINAGGIO

Questo prodotto è pronto per l'uso, e non sono necessarie ulteriori operazioni di preparazione. Il lotto imballato non aperto o la confezione del kit individuale possono essere conservati a 5—25°C fino al momento dell'uso o fino alla data di scadenza. Non surriscaldare. Non incubare o congelare prima dell'uso. Un'immagazzinaggio inappropriato può causare una perdita di efficacia. Non usare dopo la data di scadenza, che è stata stampata chiaramente sull'esterno della scatola.

DETERIORAMENTO DEL PRODOTTO

Non usare il brodo BHI della Copan se: (1) il prodotto mostra segni visibili di danni o di contaminazione; (2) ci sono indizi di perdite; (3) è stata superata la data di scadenza; (4) ci sono altri segni di deterioramento (per esempio, il terreno è torbido).

MATERIALI FORNITI

Numero di catalogo	Descrizione del prodotto	Pack Size	Suitable for Automation
474CE	3 ml di brodo BHI in tubo di polipropilene da 12X80 con tappo a vite e forma interna conica.	50 unità per confezione commerciale 6x50 unità per scatolone	NO
474CE.A	3 ml di brodo BHI in tubo di polipropilene da 12X80 con tappo a vite e forma interna conica.	50 unità per confezione commerciale 6x50 unità per scatolone	SI