

Tryptic Soy Broth, Prepared- Instructions for Use

Intended Use

BACGro™ Tryptic Soy Broth (TSB) prepared media is intended for laboratory use as a general non-selective growth media for a wide variety of organisms. It is not intended for use in diagnosis, treatment, or prevention of disease in humans. BACGro™ TSB conforms to harmonized USP/EP/JP requirements.

Product Summary

Tryptic Soy Broth – also referred to as Soybean-Casein Digest Medium, is a general purpose, non-selective growth media that supports growth of most non-fastidious Gram negative and Gram positive bacteria as well as many yeasts and molds. It also supports the growth of many obligate anaerobes when incubated anaerobically. Enzymatic digests of casein and soybean meal provide a source of nitrogen, and the inclusion of dextrose provides the main source of carbon for growth. Osmotic balance is achieved through the inclusion of sodium chloride, while dipotassium phosphate serves as a buffering agent to maintain pH.

The formulation of BACGro™ TSB conforms to the Harmonized United States Pharmacopeia (USP)¹, European Pharmacopeia (EP)² and Japanese Pharmacopeia (JP)³ Standards.

Formulation (per Liter)*

Casein Peptone	17.0 g
Soy Peptone	3.0g
Sodium Chloride	5.0 g
Dextrose	2.5 g
<u>Dipotassium Phosphate</u>	<u>2.5 g</u>
Total	30.0 g/L

*Formula may be supplemented and/or adjusted as required to meet performance criteria

Directions

For use in laboratory testing. Aseptically inoculate the medium with the desired specimen and incubate at the directed temperature and time duration required for growth promotion.

Precautions

This product is for laboratory use only and should only be used by qualified, trained laboratory personnel. Personnel should always use proper aseptic technique and observe all biohazardous precautions. All microbiological cultures should be presumed to be infectious.

Avoid using this product if it shows evidence of microbial contamination, discoloration, or other signs of deterioration.

Avoid ingestion, inhalation, or contact with skin and mucous membranes. If contact occurs, flush the area with clean water.

Quality Control Specifications

Gold Standard Diagnostics tests each lot of manufactured BACGro™ culture media utilizing appropriate control organisms and specifications as documented on the Certificate of Analysis. End users should perform quality control testing in accordance with government regulatory requirements and accreditation guidelines. For optimal growth of strict aerobes, containers should be vented during the incubation. This may be achieved by loosening the caps. The following specifications are routinely used for testing:

Appearance (prepared): Clear, light amber, with no precipitate or debris

pH (prepared): 7.1 – 7.5 at 25°C

Organism Performance:

Strain ID	Inoculum	Incubation			Result
		Time	Temp.	Environment	
<i>E. coli</i> (ATCC® 8739)	<100 CFU	18-72 hr.	20-25° C	Aerobic	Growth
<i>S. enterica</i> ser. Typhimurium (ATCC® 14028)	<100 CFU	18-72 hr.	20-25° C	Aerobic	Growth
<i>P. aeruginosa</i> (ATCC® 9027)	<100 CFU	18-72 hr.	20-25° C	Aerobic	Growth
<i>S. aureus</i> (ATCC® 6538)	<100 CFU	18-72 hr.	20-25° C	Aerobic	Growth
<i>B. subtilis</i> (ATCC® 6633)	<100 CFU	18-72 hr.	20-25° C	Aerobic	Growth
<i>C. albicans</i> (ATCC® 10231)	<100 CFU	<5 days	20-25° C	Aerobic	Growth
<i>A. brasiliensis</i> (ATCC® 16404)	<100 CFU	<5 days	20-25° C	Aerobic	Growth

Limitations of the Procedure

This product is not labeled for use as a medical device, and is not intended to diagnose, treat, or prevent disease.

Due to variation in nutritional requirements, some strains may be encountered that grow poorly in this medium.

Further biochemical or serological testing is required for the identification of organisms grown in this medium.

Storage and Expiration

BACGro™ Tryptic Soy Broth should be stored at 2 – 25 degrees Celsius.

The expiration date printed on the label is applicable to media stored as directed.

Catalog Numbers

PLM1220- Tryptic Soy Broth, 20 mL Test Tube

PLM1230- Tryptic Soy Broth, 100mL Jar

PLM1235- Tryptic Soy Broth, Bagged 100mL Jar

PLM1250- Tryptic Soy Broth, 500mL Bottle

¹ United States Pharmacopeial Convention. United States Pharmacopoeia and National Formulary (USP-NF).

² Directorate for the Quality of Medicines and the Council of Europe. The European Pharmacopoeia.

³ Pharmaceuticals and Medical Devices Agency, Ministry of Health, Labor, and Welfare. Japanese Pharmacopoeia.

Revision History:

Revision	Description	Effective Date
03	Periodic Review. Added "Avoid using this product...deterioration." under the Precautions section. Added "For optimal growth...loosening the caps." under Quality Control specifications	07-MAR-2023
02	Error-correct incubation time for <i>C. albicans</i> 10231 to <5 days	14-NOV-2022
01	Document creation	01-MAY-2020