

## Tryptic Soy Broth - Instructions for Use

### *Intended Use*

BACGro™ Tryptic Soy Broth (TSB), when prepared as directed, is intended for laboratory use as a general purpose, non-selective growth media for a wide variety of microorganisms. 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 and commonly abbreviated as TSB- 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)<sup>1</sup>, European Pharmacopeia (EP)<sup>2</sup> and Japanese Pharmacopeia (JP)<sup>3</sup> Standards.

### *Formulation\* (per Liter)*

Casein Peptone	17.0 g
Soy Peptone	3.0 g
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*

1. Add 30 g of TSB powder to 1 L of deionized water.
2. Stir to completely dissolve.
3. Autoclave at 121 degrees Celsius for 15 minutes.
4. Cool prior to use.

## 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 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. The following specifications are routinely used for testing:

Appearance (dehydrated): Light beige, homogenous, free flowing powder, free of debris

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.	30-35° C	Aerobic	Growth
<i>S. enterica</i> ser. Enteritidis (ATCC® 13076)	<100 CFU	18-72 hr.	30-35° C	Aerobic	Growth
<i>P. aeruginosa</i> (ATCC® 9027)	<100 CFU	18-72 hr.	30-35° C	Aerobic	Growth
<i>S. aureus</i> (ATCC® 6538)	<100 CFU	18-72 hr.	30-35° C	Aerobic	Growth
<i>B. subtilis</i> (ATCC® 6633)	<100 CFU	18-72 hr.	30-35° C	Aerobic	Growth
<i>C. albicans</i> (ATCC® 10231)	<100 CFU	<5 days	30-35° C	Aerobic	Growth
<i>A. brasiliensis</i> (ATCC® 16404)	<100 CFU	<5 days	30-35° 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 species or 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 – 30 degrees Celsius. Because of the hygroscopic nature of dehydrated culture media, it should be stored in a dry place and the lid should remain tightly sealed. Media should be discarded if it is not free flowing or shows discoloration.

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

### ***Catalog Numbers***

DCM1201- Tryptic Soy Broth, 500g

DCM1205- Tryptic Soy Broth, 5kg

DCM1210- Tryptic Soy Broth, 10kg

<sup>1</sup> United States Pharmacopoeial Convention. *United States Pharmacopoeia and National Formulary (USP-NF)*.

<sup>2</sup> Directorate for the Quality of Medicines and the Council of Europe. *The European Pharmacopoeia*.

<sup>3</sup> Pharmaceuticals and Medical Devices Agency, Ministry of Health, Labor, and Welfare. *Japanese Pharmacopoeia*.

Revision History:

<b>Revision</b>	<b>Description</b>	<b>Effective Date</b>
02	Periodic Review. Removed 6305 from QC (not a standard requirement). Changed 25922 to 8739 as per USP standards.	14-JUL-2022
01	Document creation	13-AUG-2019