

Fluid Thioglycollate Medium - Instructions for Use

Intended Use

BACGro™ Fluid Thioglycollate Medium, when prepared as directed, is intended for use in cultivating aerobic and anaerobic non-fastidious bacteria for sterility testing. Fluid Thioglycollate Medium is not intended for use in diagnosis, treatment, or prevention of disease in humans.

BACGro™ Fluid Thioglycollate Medium conforms to the harmonized USP/EP/JP^{1,2,3} and the FDA Bacteriological Analytical Manual⁴.

Product Summary

Fluid Thioglycollate Medium is a general-purpose medium that supports the growth of both aerobic bacteria as well as anaerobic bacteria without the use of an anaerobic chamber. The inclusion of reducing agents lowers the oxygen content of the broth. The medium also contains a small amount of agar that results in an oxygen gradient from the top of the tube to the bottom. This allows obligate aerobes and obligate anaerobes to grow in the same sample- obligate aerobes will grow at the top of the medium while obligate anaerobes will be able to grow in the bottom of the tube. Facultative organisms may grow throughout the medium.

Casein Peptone and Yeast Extract provide the nitrogen source, along with essential vitamins for growth. The oxidation-reduction potentials of the medium are lowered by Sodium Thioglycollate and L-Cystine. Resazurin acts as the oxidation indicator and will turn pink in the presence of oxygen. Dextrose is included as a carbon source while sodium chloride maintains osmotic balance. The addition of agar limits the diffusion of oxygen throughout media.

Formulation* (per Liter)

Casein Peptone	15.0 g
Yeast Extract	5.0 g
Dextrose	5.5 g
L-Cystine	0.5 g
Sodium Chloride	2.5 g
Sodium Thioglycollate	0.5 g
Resazurin	0.001 g
Agar	0.75 g
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Total	29.75 g/L

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

Directions

1. Add 29.8 g of Fluid Thioglycollate Medium powder into 1L purified water
2. Heat while stirring, bring to a soft boil for one minute to completely dissolve product
3. Autoclave at 121° Celsius for 15 minutes
4. Cool prior to use
5. Tubes should be stored with caps tightened. Any media showing pink coloration indicates exposure to oxygen. These tubes may be heated in boiling water to drive off oxygen 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): Light amber with pink layer at top. Pink layer should not exceed 10% of the tube. Clear or with slight haze.

pH (prepared): 6.9 – 7.3 at 25°C

Organism Performance:

Strain ID	Inoculum			
		Time	Temp.	Result
<i>Clostridium perfringens</i> (ATCC® 13124)	≤100 CFU	18 – 24 hrs.	37° C	Growth
<i>Clostridium sporogenes</i> (ATCC® 19404)	≤100 CFU	24 – 72 hrs.	35° C	Growth
<i>Staphylococcus aureus</i> (ATCC® 6538)	≤100 CFU	24 – 72 hrs.	35° C	Growth
<i>Pseudomonas aeruginosa</i> (ATCC® 9027)	≤100 CFU	24 – 72 hrs.	35° C	Growth
<i>Bacillus subtilis</i> (ATCC® 6633)	≤100 CFU	24 – 72 hrs.	35° C	Growth
<i>Candida albicans</i> (ATCC® 10231)	≤100 CFU	≤5 days	35° C	Growth
<i>Aspergillus brasiliensis</i> (ATCC® 16404)	≤100 CFU	≤5 days	35° C	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.

Storage and Expiration

BACGro™ Fluid Thioglycollate Medium 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

DCM3201- Fluid Thioglycollate Medium, 500g

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*.

⁴ Food and Drug Administration. Bacteriological analytical manual, 8th ed., AOAC International, Gaithersburg, MD.