BACGro™ Culture Media

GOLD STANDARD DIAGNOSTICS

Fluid D, Prepared - Instructions for Use

Intended Use

BAC*Gro*™ Fluid D is intended for laboratory use as a diluent or rinse for samples containing either lecithin or oil, or for verifying the efficacy of disinfecting/sterilization processes. Fluid D is non-toxic to microorganisms. It is not intended for use in diagnosis, treatment, or prevention of disease in humans. BAC*Gro*™ Fluid D conforms to harmonized USP/EP/JP requirements.

Product Summary

Fluid D is used as a diluting and rinsing fluid. For samples containing lecithin or oil, Fluid D is used in membrane filtration testing techniques. Peptone is included to provide osmotic balance with minimal nutrition, and the inclusion of Polysorbate 80 serves as a neutralizing agent.

The formulation of BAC*Gro*™ Fluid D conforms to the Harmonized United States Pharmacopeia (USP)[1] , European Pharmacopeia (EP)[2] and Japanese Pharmacopeia (JP)[3] Standards.

Formulation (per Liter)*

Casein Peptone	1.0 g
Polysorbate 80	1.0 g

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

Directions

For use in laboratory testing. Observe laboratory protocols for use as a diluting or rinsing fluid.

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 (i.e., dark amber), 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 BAC*Gro*™ 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, colorless, free of precipitate or excessive debris
pH (prepared): 6.9 – 7.3 at 25°C
Organism Performance: Toxicity testing is performed by inoculating Tryptic Soy Broth tubes in duplicate, with one tube containing 1mL of Fluid D. Growth should be equivalent in tubes with and w/out Fluid D.

Strain ID	Inoculum	Incubation			Result
		Time	Temp.	Environment	
P. aeruginosa (ATCC® 9027)	≤100 CFU	18-72 hr.	20-25° C	Aerobic	Growth
B. subtilis (ATCC® 6633)	≤100 CFU	18-72 hr.	20-25° C	Aerobic	Growth
C. albicans (ATCC® 10231)	≤100 CFU	18-72 hr.	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.

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

Storage and Expiration

BAC*Gro*™ Fluid D should be stored at 2 – 25°C.

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

Catalog Numbers

PLM1550 – Fluid D, 600mL 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.