ARENA BioScien

Block 5, Street 9 inside The Ismailia free zone. Ismailia- Egypt
Post Code-41511
Tel.-Fax: +202 21813500/ +202 21813600
Mob.: +2 01211550941/ +2 01119225860
E-mail: sales@arenabioscientific.com
Website: www.arenabioscien.com

Clausen Medium

Clausen Medium is recommended by Nordic Pharmacopoeia Board for sterility testing.

REF: BS.1/NZ01.100.0100	100 Gram	REF: BS.1/NZ01.250.0250	250 Gram
REF: BS.1/NZ01.500.0500	500 Gram		

PRINCIPLE AND INTERPERTATION:

Clausen Medium was developed by Clausen (1). This medium is also called as HS-T (Dithionite Thioglycollate) Medium and is recommended for sterility testing by the Nordic Pharmacopoeia Board. Random sample selection is recognized by the Board and they refer to the process as microbial-contamination test. The Standard microbial contamination test is developed to establish the number of non-sterile units, if any in batch, is below a specific level. Random sampling in sufficient quantity of the bulk should be examined. In the microbial contamination test for detecting the nonsterile units, two methods can be used viz. Membrane filter method and Dilution method. The test must be performed with all precautions taken to prevent laboratory contamination. This medium is very nutritious consisting of casein enzymic hydrolysate, papaic digest of soyabean meal, yeast extract and dextrose. L-cystine and sodium thioglycollate act as reducing agents, and the essential metals help for isolating anaerobic sporeformers. Polysorbate 80 and lecithin are added in this medium to overcome the effects of cationic agents, which can exert bacteriostatic effect in vitro. This medium is clear in appearance and yellow coloured. Under aerobic conditions it turns pink. Therefore at the time of use the upper one third of the medium should be pink. The standard microbial contamination test is passed if growth is not observed in any of the tubes. Growth is examined by the appearance of turbidity in fluid or semi fluid media and by the formation of colonies on solid media.

MEDIA COMPOSITION

Item	Formula per liter of medium
- Casein enzymic hydrolysate	15.00 gm
- Peptic digest of Soy bean meal	3.000 gm
- Yeast extract	6.000 gm
- Dextrose	6.000 gm
- Sodium chloride	2.500 gm
- Dipotassium phosphate	2.000 gm
- Sodium citrate	1.000 gm
- L-Cystine	0.500 gm
- L-Asparagine	1.250 gm
-Sodium dithionite	3.500 gm
-Sodium thioglycollate	0.400 gm
-Lecithin	0.500 gm
-Magnesium sulphate	0.300 gm
-Calcium chloride	0.004 gm
-Cobalt sulphate	0.001 gm
-Cupric sulphate	0.001 gm
-Ferrous sulphate	0.001 gm
-Zinc sulphate	0.001 gm
-Manganese chloride	0.002 gm
-Resazurin	0.001 gm
- Agar	0.750 gm

Final pH (at 25°C) 7.1 ± 0.2 ** Formula adjusted, standardized to suit performance parameters.

PRECAUTIONS AND WARNINGS

Media to be handled by entitled and professionally educated person. Do not ingest or inhale.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the Clausen Medium material safety data sheet.

STORAGE AND STABILITY

BioScien Clausen Medium should be stored between 10-30°C in a firmly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to avoid lump development due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in a dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

PREPARATION

Suspend 40 grams in 1000 ml distilled water containing 3 grams polysorbate 80 and 5 grams glycerol. Heat to boiling to dissolve the medium completely. Dispense as desired and sterilize by autoclaving at 118°C for 15 minutes. Place in cool dark place till use. DO NOT RESTERILIZE the medium Note: If more than upper one-third of the medium has acquired a pink colour, the medium may be restored once by heating in a water bath or in free flowing steam until the pink colour disappears.

DETERIORATION

The color of ***BioScien*** Clausen medium is Cream to yellow homogeneous free flowing powder. Prepared medium is Light straw coloured, clear to slightly opalescent solution with upper 10% or less portion pink on standing me, media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), and contaminations.

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile petri dishes
- Incubator
- Autoclave

PERFORMANCE CHARACTERISTICS

Cultural response observed after an incubation at 35-37°C for 18-24 hours.

Organism	Growth
Bacillus subtilis ATCC 6633	luxuriant
Candida albicans ATCC 10231	luxuriant
Clostridium sporogenes ATCC 11437	luxuriant
Pseudomonas aeruginosa ATCC 27853	luxuriant
Staphylococcus aureus ATCC 25923	luxuriant
Staphylococcus epidermidis ATCC 12228	luxuriant
Streptococcus pyogenes ATCC 19615	luxuriant

SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use		Number of <n> test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

QUALITY CONTROL

To ensure adequate quality control, it is recommended that positive and negative control included in each run. If control still out of range please contact ***BioScien*** technical support.

REFERENCE

Clausen O.G., 1973, Pharmaceutica Acta Helvetiae, 48:541 P. D., 1987, Clin. Microbiol. Newsletter, 9, 176-179.