

## TM 1525 – CLAUSEN MEDIUM

### INTENDED USE

Used as sterility medium as per Nordic Pharmacopoeia Board.

### PRODUCT SUMMARY AND EXPLANATION

Clausen Medium was developed by Clausen. 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 non-sterile 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 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.

### COMPOSITION

Ingredients	Gms / Ltr
Tryptone	15.000
Soya peptone	3.000
Yeast extract	6.000
Dextrose (Glucose)	6.000
Sodium chloride	2.500
Dipotassium hydrogen phosphate	2.000
Sodium citrate	1.000
L-Cystine	0.500
L-Asparagine	1.250
Sodium dithionite	0.400
Sodium thioglycollate	0.500
Lecithin	0.300
Magnesium sulphate	0.400
Calcium chloride	0.004
Cobalt sulphate	0.001
Cupric sulphate	0.001
Ferrous sulphate	0.001
Zinc sulphate	0.001
Manganese chloride	0.002
Resazurin	0.001
Agar	0.750

## PRINCIPLE

This medium is very nutritious consisting of Tryptone, Soya peptone, yeast extract and dextrose. L-cystine and sodium thioglycollate act as reducing agents, and the essential metals help for isolating anaerobic spore-formers. Polysorbate 80 and lecithin are added in this medium to overcome the effects of cationic agents, which can exert bacteriostatic effect in vitro.

## INSTRUCTION FOR USE

- Dissolve 40 grams in 1000 ml purified / distilled water containing 3 grams polysorbate 80 and 5 grams of glycerol. Heat to boiling to dissolve the medium completely.
- Dispense into tubes or flasks 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.

## QUALITY CONTROL SPECIFICATIONS

<b>Appearance of Powder</b>	: Cream to yellow homogeneous free flowing powder.
<b>Appearance of prepared medium</b>	: Light straw coloured, clear to slightly opalescent solution with upper 10% or less portion pink on standing.
<b>pH (at 25°C)</b>	: 7.1±0.2

## INTERPRETATION

Cultural characteristics observed after incubation.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Incubation Temperature	Incubation Period
<i>Bacillus subtilis subsp. spizizenii</i>	6633	50-100	Luxuriant	35-37°C	18-48 Hours
<i>Candida albicans</i>	10231	50-100	Luxuriant	35-37°C	18-48 Hours
<i>Clostridium sporogenes</i>	11437	50-100	Luxuriant	35-37°C	18-48 Hours
<i>Pseudomonas aeruginosa</i>	27853	50-100	Luxuriant	35-37°C	18-48 Hours
<i>Staphylococcus aureus subsp. aureus</i>	25923	50-100	Luxuriant	35-37°C	18-48 Hours
<i>Staphylococcus epidermidis</i>	12228	50-100	Luxuriant	35-37°C	18-48 Hours
<i>Streptococcus pyogenes</i>	19615	50-100	Luxuriant	35-37°C	18-48 Hours



### PACKAGING:

In pack size of 500 gm bottles.

### STORAGE

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers between 25-30°C and protect from direct sunlight. Under optimal conditions, the medium has a shelf life of 4 years. When the container is opened for the first time, note the time and date on the label space provided on the container. After the desired amount of medium has been taken out replace the cap tightly to protect from hydration.

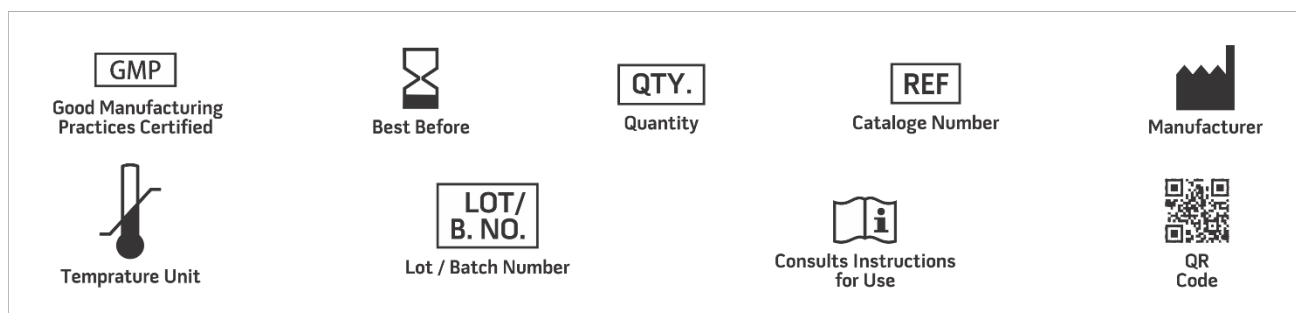
**Product Deterioration:** Do not use if they show evidence of microbial contamination, discoloration, drying or any other signs of deterioration.

### DISPOSAL

After use, prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

### REFERENCES

1. Clausen O.G., 1973, Pharmaceutica Acta Helvetiae, 48:541.
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
3. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.



**NOTE:** Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

**\*For Lab Use Only**  
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