

CM 22613 - SOYABEAN CASEIN DIGEST AGAR PLATE W/ POLYSORBATE 80, GLYCEROL W/ 5IU OF b-LACTAMASE II & 50IU OF -LACTAMASE 1/100 ML (- γ IRRADIATED) (TRIPLE PACK)**INTENDED USE**

for determine efficiency of containers, equipment, surfaces, water miscible cosmetics and inactivation penicillins, cephalosporins of first, second, third and fourth generation and penems.

PRODUCT SUMMARY AND EXPLANATION

Soyabean Casein Digest Agar with Glycerol, polysorbate 80 and beta-lactamase is used in plates for the detection and enumeration of microorganisms present on surfaces of sanitary importances and also in environmental monitoring of clean room for facilities where production of Penicillins is carried out.

COMPOSITION

Ingredients	Gms / Ltr
Agar	15.000
Casein enzymic hydrolysate	15.000
Glycerol	10.000
Sodium chloride	5.000
Papaic digest of Soybean meal	5.000
Polysorbate 80 (Tween 80)	5.000
Beta-lactamase I	500 IU
Beta-lactamase II	50 IU

PRINCIPLE

Casein enzymic hydrolysate and papaic digest of soyabean meal provide nitrogenous compounds and other nutrients essential for microbial replication. and polysorbate 80 (Tween 80) are neutralizers reported to inactivate residual disinfectants from where the sample is collected. Lecithin neutralizes quaternary ammonium compounds and polysorbate 80 neutralizes phenolic disinfectants, hexachlorophene, formalin and with lecithin ethanol. Beta-lactamase I and II added in the medium will inactivate the beta-lactam antibiotics thus enabling the growth of resistant strains present in the environment of clean rooms where production of antibiotics is carried out.

INSTRUCTION FOR USE

Either streak, inoculate or surface spread the test inoculum aseptically on the plate. Alternatively, these plates can also be used as settle plates for environmental monitoring.

QUALITY CONTROL SPECIFICATIONS

Appearance	:	Light amber color, clear to slightly opalescent gel.
Quantity of Medium	:	15-18 ml of medium in 55 mm plates.
pH (at 25°C)	:	7.3± 0.2
Dose of irradiation:	:	15-25 kGy
Sterility Check	:	Passes release criteria



INTERPRETATION

Growth Promotion test was carried out and growth was observed after incubation. Recovery rate is considered 100% for bacteria growth on Soya Agar and fungus growth on Sabouraud Dextrose Agar. Simultaneously, cultural characteristics was observed on plates which were seeded with 1 mcg per ml respective antibiotic or Minimum Inhibitory Concentration (MIC).

Growth Promotion Test

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Recovery	Incubation Temperature	Incubation Period
Bacillus subtilis	6633	50-100	Luxuriant	>=70%	30-35°C	18-24 hours
Staphylococcus aureus	25923	50-100	Luxuriant	>=70%	30-35°C	18-24 hours
Escherichia coli	25922	50-100	Luxuriant	>=70%	30-35°C	18-24 hours
Pseudomonas aeruginosa	27853	50-100	Luxuriant	>=70%	30-35°C	18-24 hours
Streptococcus pneumonia	6305	50-100	Luxuriant	>=70%	30-35°C	18-24 hours
Salmonella typhimurium	14028	50-100	Luxuriant	>=70%	30-35°C	18-24 hours
Enterococcus faecalis	29212	50-100	Luxuriant	>=70%	30-35°C	18-24 hours
Candida albicans	10231	50-100	Luxuriant	>=70%	20-25°C	<=5 days
Aspergillus brasiliensis	16404	50-100	Luxuriant	>=70%	20-25°C	<=5 days

Culture Response

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Recovery	Incubation Temperature	Incubation Period
Escherichia coli	25922	50-100				
w/o antibiotic			Luxuriant	>=70%	30-35°C	18-24 hours
w/ Cephalothin			Luxuriant	>=70%	30-35°C	18-24 hours
w/ Cefotaxime			Luxuriant	>=70%	30-35°C	18-24 hours
w/ Ceftazidime			Luxuriant	>=70%	30-35°C	18-24 hours
w/ Imipenem			Luxuriant	>=70%	30-35°C	18-24 hours
w/ Ertapenem			Luxuriant	>=70%	30-35°C	18-24 hours
w/ Meropenem			Luxuriant	>=70%	30-35°C	18-24 hours
Staphylococcus aureus	25923	50-100				
w/o antibiotic			Luxuriant	>=70%	30-35°C	18-24 hours
w/ Penicillin			Luxuriant	>=70%	30-35°C	18-24 hours
w/ Cephalothin			Luxuriant	>=70%	30-35°C	18-24 hours
w/ Cefotaxime			Luxuriant	>=70%	30-35°C	18-24 hours
w/ Ceftazidime			Luxuriant	>=70%	30-35°C	18-24 hours
w/ Imipenem			Luxuriant	>=70%	30-35°C	18-24 hours
w/ Ertapenem			Luxuriant	>=70%	30-35°C	18-24 hours
w/ Meropenem		Luxuriant	>=70%	30-35°C	18-24 hours	



PACKAGING:

Triple layered packing containing 5 No. of plates with one silica gel desiccant bag packed inside it.

STORAGE

On receipt, store the plates at 15–30 °C. Avoid freezing and overheating. Do not open until ready to use. Prepared plates stored in their original sleeve wrapping until just prior to use may be inoculated up to the expiration date and incubated for recommended incubation times. Allow the medium to warm to room temperature before inoculation. Product Deterioration: Do not use plates if they show evidence of microbial contamination, discoloration, drying, cracking or other signs of deterioration.

DISPOSAL

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

REFERENCES

1. The United States Pharmacopoeia. 2009. Amended Chapters 61, 62 & 111, The United States Pharmacopoeia Convention Inc., Rockville, MD.
2. Hall and Hartnett, 1964, Public Hlth. Rep., 79:1021.
3. Richardson (Ed)., 1985, Standard Methods for the Examination of Dairy Products, 15th ed., APHA, Washington, D.C.
4. MacFaddin J.F., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. I, Williams and Wilkins, Baltimore.
5. Brummer, 1976, Appl. Environ. Microbiol., 32:80.
6. Erlandson A.L. Jr and Lawrence C.A. 1953, Inactivating medium for hexachlorophene (G-11) types of compounds and some substituted phenolic disinfectants, Science, 118, 274-276.
7. Favero (Chairm), 1967, Biological Contamination Control Committee, a state of the art report., Am. Assoc. for contamination control

**QTY.**

Quantity

**LOT/
B. NO.**

Lot / Batch Number



Temperature Unit



Manufacturer



Best Before

**GMP**Certification of
Good Manufacturing Practices

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

