

CM 22607 - SOYABEAN CASEIN DIGEST AGAR PLATE W/ LECITHIN AND TWEEN 80 W/ β - LACTAMASE II (γ -IRRADIATED) (TRIPLE PACK)

INTENDED USE

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

PRODUCT SUMMARY AND EXPLANATION

Soyabean Casein Digest Agar with Tween 80, Soya lecithin and beta-lactamase II is used in plates for the detection and enumeration of microorganisms present on surfaces of sanitary importance and also in environmental monitoring of clean room for facilities where production of β -lactam group of antibiotics is carried out.

The media are gamma irradiated in the packaging material to assure a reduction of the microbial load potentially present in the medium, on the dishes, and on the packaging materials. Gamma- irradiation of the product is indicated by an orange to red color of the irradiation indicator stripe on the inner label.

COMPOSITION

Ingredients	Gms / Ltr
Casein enzyme hydrolysate	15.000
Agar	15.000
Papaic digest of Soybean	5.000
Sodium chloride	5.000
Polysorbate 80 (Tween 80)	5.000
Lecithin	0.700
Beta-lactamase II	500.000 IU/Ltr

PRINCIPLE

Medium contains Casein enzymic hydrolysate and papaic digest of soyabean meal which provide nitrogenous compounds and other nutrients essential for microbial replication. Sodium chloride is added to maintain cellular osmotic equilibrium. Lecithin and Tween 80 are neutralizers added to the formulation to inactivate germicidal or disinfectant residues. Quaternary ammonia compounds are neutralized by lecithin, while phenolic disinfectants and hexachlorophene are neutralized by tween 80. Together, lecithin and Tween 80 neutralize ethanol. Addition of beta-lactamase II enables the growth of resistance strains present in the environment of clean room by inactivating the beta-lactam antibiotics. Agar is used as a solidifying agent.

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	:	25 ml of medium in 90 mm plates.
pH (at 25°C)	:	7.3 ± 0.2
Dose of irradiation:	:	9-20 kGy
Sterility Check	:	Passes release criteria



INTERPRETATION

GrowthPromotion 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
Aspergillusbrasiliensis	16404	50-100	Luxuriant	>=70%	20-25°C	<=5 days

Cultural 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:

Triplelayeredpacking containing 5 No. of plates with one silica gel desiccant bag packed inside it.

STORAGE

Onreceipt, 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. Hall and Hartnett, 1964, Public Hlth. Rep., 79:1021.
2. Richardson (Ed.), 1985, Standard Methods for the Examination of Dairy Products, 15th ed., APHA, Washington, D.C.
3. MacFaddin J.F., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. I, Williams and Wilkins, Baltimore.
4. Brummer, 1976, Appl. Environ. Microbiol., 32:80.
5. Favero (Chairman), 1967, Biological Contamination Control Committee, a state of the art report., Am. Assoc. for contamination control.
6. Murray PR, Baron, Pfaller, and Tenover (Eds.), 2003, In Manual of Clinical Microbiology, 8th ed., ASM, Washington, D.C.

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.

*For Lab Use Only

