

CM 22267 - FOOD PATHOGEN DETECTION KIT

INTENDED USE

For rapid detection of food pathogens such as *E. coli*, *E. coli O157: H7*, *Salmonella*, *Listeria*, *Staphylococcus* and *Clostridium* species.

PRODUCT SUMMARY AND EXPLANATION

Safety of the products on microbiological attributes has been a major concern all over the world for food and allied industries. Regulatory authorities have made it mandatory to prove the absence of pathogenic organisms such as *E. coli*, *Klebsiella*, *pneumonia*, *E. coli O157: H7*, *Salmonella*, *Shigella*, *Listeria*, *Staphylococcus* and *Clostridium* to confirm the safety of the raw and processed samples. Conventional methods take up to 48 hours to one week to identify the presence or absence of the organisms. Many of the food products are "easily perishable" that necessitated the faster and reliable methods to prove their safety. Food Pathogen Detection kit significantly reduces the time needed to obtain test result to less than 12 hours. This kit works on growth on growth based biochemical reactions resulting in chromogenic reaction, sugar fermentation and H₂S production depending upon the target organism.

KIT CONTAINS

A) Stomacher bags for sampling processing.

- 1) Small bag of 390 ml capacity.
- 2) Medium Bag of 710 capacity
- 3) Large of 1.63 L Capacity

B) Enrichment Medium for Sampling Processing

- 1) Sterile enrichment medium bud

C) Testing Medium

- 1) Differential Food Pathogen Testing Medium
- 2) Aureus Confirmation test medium
- 3) Listeria Confirmation Test Medium
- 4) Clostridium Confirmation Test Medium

Note: Stomacher bags of different sizes are supplied in different kits as specified. Enrichment Medium and Testing Medium are common and are supplied.

PRINCIPLE

Enrichment: Unfavorable physiochemical parameters present in the food system cause physiological stress and injury to the organisms in food samples. Enrichment step is done to resuscitate these physiologically stressed or injured cells and to increase the target pathogen concentration in a sample. Appropriate amount of sample (as per the directions) is enriched in the enrichment medium provided with the kit and incubated for 4-6 hours and proceeded for confirmation of pathogenic organisms.

Differential Food Pathogen Determination: This kit is used for the simultaneous detection of common enteric food pathogens such as *Klebsiella*, *E. coli*, *Enterobacter*, *Salmonella* and *Shigella*. 20ml of the enriched is added to the differential food pathogen testing medium and incubated at 35-37°C for 4-6 hrs. The medium contains phenol red as an indicator and sorbitol as the fermenting sugar. Sorbitol fermenters such as *Klebsiella pneumoniae* and *Enterobacter aerogenes* give yellow colour to the medium because of the fermentation of carbohydrates, causing the reduction of pH



of the medium. Non-Sorbitol fermenters such as *E.coli O157: H7* remain pink colour. *E. coli* cleaves the chromogenic mixture in the medium as well ferments sorbitol and hence imparts green color to the medium. The medium contains H₂S detection system, wherein *Salmonella* gives black color to the medium. The medium thereby differentiates between Sorbitol fermenters, Non-Sorbitol fermenters, H₂S producers and non-producers.

Aureus Confirmation Test: The confirmation of *S.aureus* is carried out by coagulation, to check the presence of the enzyme coagulase. The medium provided is rehydrated with 0.6ml of the enrichment sample. If *S.aureus* is present clot formation will occur within 4-6 hrs.

Listeria Confirmation Test: The confirmation of *Listeria* is based on their ability to use and hydrolyze esculin. The selective agents in the medium help in eliminating the contaminating microorganisms. 5 ml of the enriched food sample is added to selective *Listeria* medium and the tube is incubated at 35-37°C for 6-8 hrs. The presence of *Listeria* is indicated by the blackening of the medium.

Clostridium Confirmation Test: 5ml of the enriched sample is inoculated in *Clostridium* confirmation medium. The tube is mixed well and incubated anaerobically for a period of 12-24 hrs. The formation of stormy fermentation indicates the presence of *Clostridium*.

INSTRUCTION FOR USE

1. The sample collection and processing of food sample under study should be as per standard methods.
2. Enrich processed food samples in Stomacher bags on adding the medium. For this, suspend sterile enrichment medium bud in distilled/purified water. Shake and mix evenly to dissolve the bud completely. Add sample dilution to be enriched as per following.

Food Pathogen Detection Kit	Capacity of Stomacher bags	Quantity of distilled water/purified water for suspending enrichment bud	No. of sterile enrichment bud to be suspending	Sample to be added
08S	390 ml	250 ml	1 Number	25g / 25 ml
08M	710 ml	500 ml	2 Number	50g / 50ml
08L	1.63L	1000 ml	4 Number	100g / 100ml

3. Incubate the prepared suspension in Stomacher bags at 35-37°C for 4-6 hours.
4. Inoculate enriched sample into testing medium as follow

Food Pathogen Detection Kit	Differential Food Pathogen Testing Medium	Aureus Confirmation test medium	Listeria Confirmation Test Medium	Clostridium Confirmation Test Medium
08S/ 08M/ 08L expected results on incubation at 35-37°C	20 ml colour change of medium as yellow, green or black in 4-6 hours	0.6ml clot formation in 4-6 hours	5 ml growth with blackening in 6-8 hours	5 ml stormy fermentation in 12-24 hours.

5. Incubate at 35-37°C for 4-8 upto 12 hours. Interpret the colour change, clot formation, blackening of medium and stormy fermentations in respective media's as cited above.
6. Please note that, incubate for a period of 24 hours before discarding as negative.



QUALITY CONTROL SPECIFICATIONS

Appearance of medium : Purple coloured clear solution
Sterility Check : Passes release criteria

INTERPRETATION

Cultural response observed by incubation at 35-37°C.

Microorganisms	ATCC	Growth in Enrichment Medium (4-6 hours)	Differential Food Pathogen Testing Medium (4-6 hours)	<i>Aureus</i> Confirmation test medium (4-6 hours)	<i>Listeria</i> Confirmation Test Medium (6-8 hours)	<i>Clostridium</i> Confirmation Test Medium (10-24 hours)
<i>Escherichia coli</i>	25922	Luxuriant	Green Colour	No Clot Formation	Inhibited	No fermentation
<i>Staphylococcus aureus</i>	25923	Luxuriant	No Colour Change	Clot Formation	Inhibited	No fermentation
<i>Salmonella Typhi</i>	6539	Luxuriant	Blackening of the medium	No Clot Formation	Inhibited	No fermentation
<i>Salmonella Typhimurium</i>	14028	Luxuriant	Blackening of the medium	No Clot Formation	Inhibited	No fermentation
<i>Listeria Monocytogenes</i>	19112	Luxuriant	No Colour Change	No Clot Formation	Growth with blackening of the medium	No fermentation
<i>Clostridium perfringens</i>	12924	Luxuriant	No Colour Change	No Clot Formation	Inhibited	Stormy fermentation
<i>Klebsiella pneumoniae</i>	13883	Luxuriant	Yellow	No Clot Formation	Inhibited	No fermentation
<i>Enterobacter aerogenes</i>	13048	Luxuriant	Yellow	No Clot Formation	Inhibited	No fermentation
<i>E.coli O157: H7</i>	-	Luxuriant	Pink	No Clot Formation	Inhibited	No fermentation

STORAGE

Store the medium in a dark and dry place 10- 25°C and protect from direct sunlight. The medium may be used up to the expiration date and incubated for the recommended incubation times.

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

DISPOSAL

After use, prepared media, specimen/sample containers and other contaminated materials must be sterilized before discarding as per standard protocol.



QTY.
Quantity

**LOT/
B. NO.**
Lot / Batch Number


Temperature Unit


Manufacturer


Best Before

GMP
Certification of
Good Manufacturing Practices

REF
Catalogue No.

EC REP MedNur GmbH
Buckhorn 10,
48163 Münster, Germany
Authorized Representative


European Conformity


Consults Instructions for use :


QR
Code

IVD
For In Vitro Diagnostic Use

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

