

NFL Aseptic Validation Medium (NCM0007)

Intended Use

National Food Laboratory Aseptic Validation Medium is used for the cultivation of mesophilic or thermophilic spoilage microorganisms in food in a laboratory setting. National Food Laboratory Aseptic Validation Medium is not intended for use in the diagnosis of disease or other conditions in humans.

Description

Foods may spoil either due to biological or chemical reasons. Spore-forming bacteria, e.g., *Clostridium* and *Bacillus*, are important because of their heat resistant (thermophilic) nature. In addition, there are other microorganisms which are not heat resistant (mesophilic) but enter through the leakage of the container during cooling.

Examples of spoilage type thermophilic microorganisms are flat-sour and sulfide spoilage and can be found in corn, peas and spinach. Mesophilic microorganisms include putrefactive anaerobes, butyric anaerobes, and aciduric flat-sour, and can be found in tomatoes and peas.

In the 1930's, the National Canners Association specified use of Dextrose Tryptone Agar for isolating "flat sour" organisms from food products.

National Food Laboratory Aseptic Validation Medium is a general purpose medium for the recovery of aerobic and facultative organisms used in the validation and commissioning of aseptic filling systems. This medium is ideally suited for the spore-forming organisms used in the validation of steam, hydrogen peroxide, and peracetic acid sterilization systems.

Typical Formulation

Enzymatic Digest of Casein	10.0 g/L
Dextrose	5.0 g/L
Yeast Extract	1.0 g/L
Bromocresol Purple	0.04 g/L

Final pH: 6.9 ± 0.2 at 25°C

Formula may be adjusted and/or supplemented as required to meet performance specifications.

Precaution

Refer to SDS

Preparation

Laboratory Use

1. Dissolve 16 g of the medium in one liter of purified water.
2. Heat with frequent agitation and boil for one minute to completely dissolve the medium.
3. Autoclave at 121°C for 15 minutes.

In-Plant Commissioning Use

1. In mix system dissolve 16 grams of the medium per liter of water.
2. Agitate for 20 minutes to dissolve the medium.
3. Process at minimum $F_0 = 8.0$ (hold-tube process).

Technical Specification Sheet



Quality Control Specifications

Dehydrated Appearance: Powder is homogeneous, free flowing, and beige to tan, with or without greenish tinge.

Prepared Appearance: Prepared medium is clear, purple and with no precipitate.

Expected Cultural Response: Cultural response in National Food Laboratory Aseptic Validation Medium incubated at the appropriate atmosphere and temperature and examined for growth at 18 – 48 hours.

Microorganism	Approx. Inoculum (CFU)	Test Parameters	Expected Results
<i>Geobacillus stearothermophilis</i> ATCC® 7953	100 - 1000	18 – 24 hours at 55 ± 2°C	Growth, yellow
<i>Bacillus subtilis</i> ATCC 19659	100 -1000	40 – 48 hours at 30 ± 2°C	Growth, red-purple

Test Procedure

Refer to appropriate references for specific procedures.

Results

Organisms that produce acid from dextrose, such as *Bacillus stearothermophilus* and other “flat-sour” organisms, are detected by the color change of the medium from purple to yellow.

Expiration

Refer to expiration date stamped on the container. The dehydrated medium should be discarded if not free flowing, or if appearance has changed from the original color. Expiry applies to medium in its intact container when stored as directed.

Limitations of the Procedure

Due to varying nutritional requirements, some strains may be encountered that grow poorly or fail to grow on this medium.

Storage

Store sealed bottle containing the dehydrated medium at 2 - 30°C. Once opened and recapped, place container in a low humidity environment at the same storage temperature. Protect from moisture and light by keeping container tightly closed.

References

1. Vanderzant, C. and D. F. Splittstoesser (eds.). Compendium of methods for the microbiological examination of foods, 4th ed. American Public Health Association, Washington, D.C.
2. <https://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm>
3. National Canners Association. 1933. Bacterial standards for sugar.

