

National Food Laboratory Aseptic Validation Medium - Instructions for Use

Intended Use

BACGro™ National Food Laboratory (NFL) Aseptic Validation Medium is used for the growth and isolation of mesophiles and thermophiles from food and food processing facilities. Aseptic Validation Medium is not intended for use in diagnosis, treatment, or prevention of disease in humans.

Product Summary

National Food Laboratory Aseptic Validation Medium is used as a general medium to promote growth of aerobic bacteria and facultative anaerobic bacteria present in spoiled food products and is suitable for use in the validation and commissioning of aseptic filling processes. It is designed to recover spore forming organisms that are used to validate many common sterilization processes, such as steam, hydrogen peroxide, or peracetic acid.

Casein peptone provides a source of carbon and nitrogen required for growth of organisms while yeast extract serves as a source of essential vitamins and nutrients. The presence of glucose serves as a fermentable carbohydrate for organisms such as *Geobacillus stearothermophilus* and other flat sour organisms. The production of acid from glucose is detected by the inclusion of bromocresol purple, which turns from purple to yellow in response to acid production.

Formulation (per Liter)*

| | |
|---------------------------|---------------|
| Casein Peptone | 10.0 g |
| Dextrose | 5.0 g |
| Yeast Extract | 1.0 g |
| <u>Bromocresol Purple</u> | <u>0.04 g</u> |
| Total | 16 g/L |

*Formula may be supplemented and/or adjusted as required to meet performance criteria

Directions

Laboratory Use

1. Dissolve 16 g of National Food Laboratory Aseptic Validation Medium in 1L purified water.
2. Heat with agitation to create an aqueous solution.
3. Autoclave at 121 degrees Celsius for 15 minutes.
4. Cool prior to use.

In-Plant Commissioning/Validation Use

1. Dissolve 16 g of National Food Laboratory Aseptic Validation Medium per Liter of purified water in mixing system.
2. Mix for 20 minutes to ensure powder is completely dissolved.
3. Process at a minimum $F_0 = 8.0$.

Precautions

This product is for laboratory use only and should only be used by qualified, trained laboratory personnel. Personnel should always use proper aseptic technique and observe all biohazardous precautions. All microbiological cultures should be presumed to be infectious.

Avoid ingestion, inhalation, or contact with skin and mucous membranes. If contact occurs, flush the area with clean water.

Quality Control Specifications

Gold Standard Diagnostics tests each lot of manufactured BACGro™ culture media utilizing appropriate control organisms and specifications as documented on the Certificate of Analysis. End users should perform quality control testing in accordance with government regulatory requirements and accreditation guidelines. The following specifications are routinely used for testing:

Appearance (dehydrated): Gray to beige, homogenous, free flowing powder, free of debris

Appearance (prepared): Clear, purple, with no precipitate or debris

pH (prepared): 6.7 – 7.1 at 25°C

Organism Performance:

| Strain ID | Inoculum | Incubation | | | Result |
|---|----------------|------------|---------|-------------|------------------------|
| | | Time | Temp. | Environment | |
| <i>Geobacillus stearothermophilus</i> (ATCC® 7953) | 100 – 1000 CFU | 18-24 hr. | 55±2° C | Aerobic | Growth – Yellow |
| <i>B. subtilis</i> (ATCC® 6633) | 100 – 1000 CFU | 24-48 hr. | 30±2° C | Aerobic | Growth – Red-Purple |

Limitations of the Procedure

This product is not labeled for use as a medical device, and is not intended to diagnose, treat, or prevent disease.

Due to variation in nutritional requirements, some strains may be encountered that grow poorly in this medium.

Storage and Expiration

BACGro™ Aseptic Validation Medium should be stored at 2 – 30 degrees Celsius. Because of the hygroscopic nature of dehydrated culture media, it should be stored in a dry place and the lid should remain tightly sealed. Media should be discarded if it is not free flowing or shows discoloration.

The expiration date printed on the label is applicable to media stored as directed.

Catalog Numbers

DCM2201- NFL Aseptic Validation Medium, 500g

DCM2205- NFL Aseptic Validation Medium, 5kg

DCM2210- NFL Aseptic Validation Medium, 10kg

DCM2250- NFL Aseptic Validation Medium, 50kg