soleris®

Total Viable Count, UHT

Product Number: (NF-105)

Pictured: NF-105 vial uninoculated (left) and inoculated vial (right).

Introduction

The Nonfermenting Total Viable Count, UHT (NF-105) Medium Vial (5 mL), allows for greater inclusivity with a shorter detection time in sterility testing. As organisms grow in the broth medium, the carbon dioxide (CO_2) produced diffuses through a membrane layer into a soft agar plug containing a dye indicator. The Soleris® instrument reads the color change in the dye. The membrane layer also serves as a barrier, eliminating product interference with the reading frame.

Materials Required

1. NF-105, Nonfermenting Total Viable Count (NF-105) Medium

Dependent on Sample Tested

1. Butterfield's Phosphate Buffer (BPB-99)

Vial Specifications

1. Vial pH is 7.3 ± 0.2
2. Vial sample capacity up to 5.0 mL

Vial Preparation

1. Remove NF-TVC vials from the refrigerator and allow to equilibrate to room temperature.

Sample Preparation

1. Add sample directly or, if using dilute-to-specification, complete the dilution required (See Soleris Manual, section 1.7).
    a. For USP testing, perform 1:10 dilution by adding 10 g of sample in 90 mL of Tryptic Soy Broth or designated neutralization broth.
        i. Check pH and adjust if necessary, to 7.0 ± 1.0
    b. For all other testings, perform 1:10 dilution by adding 11 g of sample in 99 mL of Butterfield's Phosphate Buffer.
        i. Check pH and adjust if necessary, to 7.0 ± 1.0
2. If necessary, use Butterfield's Phosphate Buffer to create the dilutions to the appropriate specification.

Pre-incubation for sterility testing

1. Pre-incubate the sample for 48–72 hours at 32–37°C as optimized for the customer.
2. Shake the container to mix any organisms present in the product thoroughly.
3. After the pre-incubation, test the sample by adding up to 5.0 mL of the sample to the vial.

Inoculation of vial

1. Inoculate the vial with no more than 5.0 mL of the sample to be tested. If using the dilute-to-specification method, add the volume of the appropriate dilution required.
2. Cap the vial and gently invert three times to mix the sample. Keep cap tight.
3. Insert the vial into the Soleris instrument set at 32-35°C or as indicated by the trainer. Adjusting parameters without consulting NEOGEN Technical Services is not recommended.

Algorithm utilized:

Test	Threshold	Skip	Shuteye	Test Duration	Temperature
NF-105	10	2	30	24 hours	32–35°C

*If shuteye detections are observed at 2.8 hours, the parameters may need to be adjusted based on product matrix. Please consult Soleris Technical Services for assistance.

CAUTION: Products containing CO_2 releasing compounds (e.g., ascorbic acid, calcium carbonate, or calcium ascorbate) need to be carefully validated as reactions with the vial chemistry may occur, causing false-positive results.

Disclaimers:

Information provided is based on validation procedures that NEOGEN performed in NEOGEN Laboratories, deviation from procedures are possible, but should be discussed with NEOGEN Technical Services.

Inspect the appearance of the vials before use.

Specific product matrices may require new parameters. For more information, contact NEOGEN Technical Services.

If shuteye detections are observed, the threshold may need to be adjusted based on the product matrix. Specific product matrices may require new parameters. For more information, contact NEOGEN Technical Services.

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