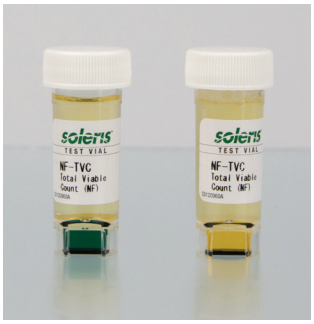
soleris®

Non-Fermenting Total Viable Count Vial

Product No. NF-TVC

Instructions for use in BioLumix Instrument



Soleris® vial uninoculated (left) and inoculated vial (right).

The Total Viable Count (NF-TVC) Vial (9 mL). The vial has broad inclusivity and an assay time of 24 hours or less for most applications. 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 color change in the dye is read by the BioLumix® instrument. The membrane layer also serves as a barrier, eliminating product interference with the reading frame.

Materials Required:

1. NF-TVC, Non-fermenting Total Viable Count (NF-TVC) vial
2. For USP Testing: Tryptic Soy broth (BLX-TSB90)
   a. If required, use a designated neutralization broth, such as D/E Neutralizer, TAT Broth, Modified Letheen Broth, etc.

Dependent on Sample Tested:

1. Butterfields's Phosphate Buffer (BPB-99)
2. Sterile 1 N to 5 N sodium hydroxide (NaOH) and/or hydrochloric acid (HCl)
3. pH meter or pH paper
4. Butterfield's Phosphate Buffer, 90 mL (6654)

Vial Specifications

1. Vial pH is 7.3 ± 0.2
2. Vial sample capacity up to 1.0 mL

Vial Preparation

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

Sample Preparation

1. For non-USP Testing, add the sample directly or prepare a 1:10 dilution by adding 11 g of sample to 99 mL of sterile Butterfield's Phosphate Buffer.
2. For USP testing, perform 1:10 dilution by adding 10 g of sample in 90 mL of Tryptic Soy Broth (See Neogen Rapid Microbiology System Validation Book, Introduction, p.5) or designated neutralization broth.
   a. Check pH and adjust, if necessary, to 7.0 ± 1.0.
3 If using the dilute-to-specification method, complete the dilution required.

Inoculation of Vial

1. Inoculate the vial with no more than 1.0 mL and no less than 0.10 mL of the sample to be tested. If using dilute-to-specification method, add the volume of the appropriate dilution required.
2. Cap the vial and gently invert 3 times to mix sample. Keep cap tight.
3. Insert the vial into the BioLumix instrument set at 35°C or as indicated by trainer. The incubation temperature and test duration can be optimized if required. It is not recommended to adjust parameters without consulting Neogen Technical Services.

Algorithm Utilized:

Test	Test Type	Detection Level	Resolution	Ignore	Test Duration	Temp
NF-TVC	Yellow	7	1	30	22–24 Hours	35°C

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 is possible, but should be discussed with Neogen Technical Services.

Appearance of the vials should be inspected prior to use.

Certain product matrices may require parameter adjustments, including increased test duration. For more information contact Neogen Technical Services.

Samples may need to be pH adjusted for all vials.

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