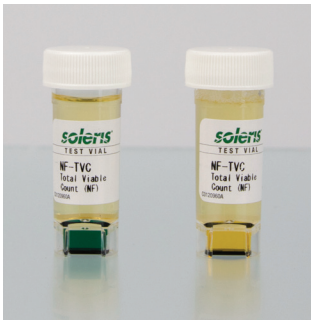
soleris®

Non-Fermenting Total Viable Count Vial

Product No. NF-TVC

Instructions for use in Soleris Instrument



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

The Total Viable Count (NF-TVC) Vial (9 mL) is suitable for sterility testing in a variety of matrices. 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 Soleris instrument. The membrane layer also serves as a barrier, eliminating product interference with the reading frame.

In an AOAC Research Institute Performance Tested Method SM License # 071203 study, the Soleris NF-TVC vial was found to be an effective procedure for semi-quantitative determination of total aerobic count in the following sample types: raw chicken, deli ham, lettuce, almonds, black pepper, cheesecake, ice cream mix, nonfat dry milk and cocoa powder. Test duration is 24 hours, with the exception of cocoa powder, which is 27 hours.

Materials Required:

NF-TVC, Non-fermenting Total Viable Count (NF-TVC) vial

Dependent on Sample Tested:

1. Butterfield'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. 4. 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.

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. 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 testing, perform 1:10 dilution by adding 11 g of sample in 99ml of Butterfields 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.

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 Soleris instrument set at 32–35°C or as indicated by trainer. The incubation temperature and test duration can be optimized within the listed ranges for different product types. It is not recommended to adjust parameters without consulting Neogen Technical Services.

Algorithm Utilized:

Test	Threshold	Skip	Shuteye	Duration	Temperature
NF-TVC	10	1	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.

Sterility Testing

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 thoroughly mix any organisms present in the product.
3. After the pre-incubation, test the sample by adding up to 1.0 mL of the sample to the vial.

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 Soleris instrument set at 32-35°C or as indicated by trainer. The incubation temperature and test duration can be optimized within the listed ranges for different product types. It is not recommended to adjust parameters without consulting Neogen Technical Services.

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

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