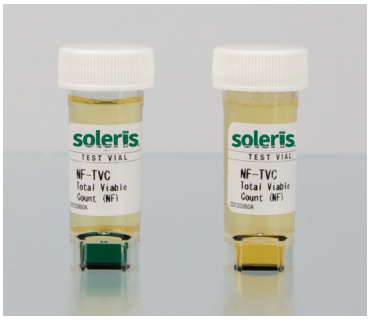
soleris

Total Viable Count Medium & Sterility Testing Vials

Product Number: NF-TVC (9 mL) | NF-105 (5 mL)



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

For use with the Soleris Microbial Detection System

STORAGE REQUIREMENTS

Store refrigerated (2-8°C). Do not freeze.

EXPIRATION DATE

NF-TVC – 12 months from date of manufacture
NF-105 – 6 months from date of manufacture

MATERIALS PROVIDED

- NEOGEN item NF-TVC includes 1 box of 100 Total Viable Count Media Vials (9mL)
- NEOGEN item NF-105 includes 1 box of 100 Total Viable Count Media Vials (5mL)

NF-TVC VIAL SPECIFICATIONS

- Vial pH is 7.1 - 7.5
- Vial sample capacity is up to 1 mL

NF-105 VIAL SPECIFICATIONS

- Vial pH is 7.1 - 7.5
- Vial sample capacity is up to 5 mL

INTENDED USE

The NF-TVC and NF-105 are highly sensitive vials designed for sterility testing in UHT products and determining the level of non-fermenting bacteria, yeast and mould present in a commodity. These vials can also be used for total viable counts in all areas of food production including nutraceuticals, raw materials, manufacturing, finished products, storage and distribution.

INTENDED USER

The NF-TVC and NF-105 vials are designed for use by all personnel involved in sterility testing, quality control personnel and others familiar with commodities that require TVC testing. Training and support is available through NEOGEN.

THE MICROORGANISM

A Total Viable Count (TVC) is not microorganism specific but rather a test which estimates total numbers of viable individual microorganisms present in a set volume of sample. The TVC count includes bacteria, yeasts and mould species.

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ASSAY PRINCIPLES

The Soleris vial contains an enrichment broth medium with a CO_2 dye indicator. The reading frame contains a soft agar plug which reduces product interference with the detection of microbial growth. As microorganisms grow and respire, The CO_2 that is produced diffuses down into the soft agar plug producing a colour change that is read by optical sensors in the Soleris instrument. Light from the L.E.D. passes through the agar plug where the photo–diode reads the colour change in 'real time'. The system measures when the change is greater than the background giving a "Detection Time".

EQUIPMENT REQUIRED FOR TESTING

- Soleris Instrument (NEOGEN item SNG-INS32, BSX-128 or BSX32)
- PC pre-loaded with Soleris Fusion software (NEOGEN Item SNG-COMPUTER-UK)

MATERIALS REQUIRED BUT NOT SUPPLIED FOR TESTING

1. Sterile 1 M to 5 M NaOH and/or HCl
2. pH meter or pH paper
3. Recommended diluent, (NEOGEN item 6654 or equivalent)

ENRICHMENT/DILUENTS RECOMMENDED

1. ISO Buffered Peptone Water (NEOGEN Item NCM0015 or equivalent)
2. Peptone Salt/Maximum Recovery Diluent (NEOGEN Item NCM0085 or equivalent)
3. Butterfield's Phosphate Buffer (NEOGEN Item NCM0223, 6654, BPB-99 or equivalent)

In order to determine if the matrix being tested will impact the pH of the vial please refer to the following method and carry out a pH adjustment if necessary.

pH INVESTIGATION AND ADJUSTMENT:

Both the sample and Soleris vial used to carry out the pH investigation should not be used for further testing and should only be used to identify the required pH adjustment if needed.

Directly into the vial (To be followed if the sample will be tested without dilution) -

1. Allow the Soleris vials to equilibrate to room temperature before use.
2. Add the sample directly into the vial (1 mL or 5 mL depending on the vial of use).
3. Cap the vial and gently invert 3 times to mix sample.
4. Insert the pH probe into the vial and record the pH once it has stabilised. If out of specification add acid or base until pH falls into vial specification (7.1 - 7.5).
5. The same amount of acid or base used can then be used for the same sample type going forward.

Indirectly (To be followed only when at least a 1:10 dilution is needed for the sample) -

1. In duplicate, prepare a 1:10 dilution in sterile diluent
2. Allow dilutions to settle for 15 mins until a distinct liquid layer appears.

NOTE: Some samples may become homogenised and a liquid layer will not appear. Set one dilution aside.

3. Insert the pH probe into the liquid layer of the second dilution. Record the initial pH of the sample. It is recommended the pH of the 1:10 dilution will need to be between 7.1-7.5
4. If the initial pH is not between 7.1 - 7.5, add acid or base until the desired pH range is obtained. Record the amount of acid or base used for the adjustment and the initial and final pH values of the sample.

NOTE: If the amount of acid or base added to the 1:10 dilution exceeds 5 mL, repeat the pH adjustment using 5 M acid or base.

5. Discard the adjusted dilution. Add the recorded amount of acid or base to the dilution that was set aside. Shake and allow the sample to settle for 15 minutes if necessary. After settling, prepare serial dilutions in accordance to the required dilutions according to specifications.

Contact NEOGEN Technical Services for additional support on pH adjustment steps if further support is required.

SOLERIS INSTRUMENT SET UP

Set the instrument at 30°C or as indicated by the trainer. The incubation temperature and test duration can be optimised for different product types.

PROTOCOLS

PROTOCOL 1 - DIRECT INOCULATION (PRESENCE/ABSENCE TESTING)

1. Allow the Soleris vials to equilibrate to room temperature before use.
2. Up to 1 mL (NF-TVC) or 5 mL (NF-105) of the sample can be added directly into the vial without dilution.
3. Adjust the pH if required by adding a previously determined volume of acid or base.
4. Cap the vial and gently invert 3 times to mix sample. Slightly loosen the cap to permit air and gas exchange.
5. Insert the vial into the instrument set at 30°C for 24 hours or as indicated by the trainer.

NOTE: Samples such as fruit juices and liquid products which can be filtered can be tested using the direct inoculation method after filtration if desired, if testing pulpy juices please contact NEOGEN Technical Services for assistance.

When carrying out membrane filtration please follow the steps below:

1. Filter sample using a sterilised filtration apparatus and sterile 0.45 µm filter.
2. Filter products as specified by the in-house instructions through membrane filter.
3. Aseptically remove the filter from the apparatus, fold carefully using sterile forceps and insert into a vial equilibrated to room temperature.
4. Adjust the pH if required by adding a previously determined volume of acid or base.
5. Cap the vial and gently shake to mix sample. Slightly loosen the cap to permit gas exchange.
6. Insert the vial into the Soleris instrument set at 30°C for 24 hours or as indicated by the trainer.

TEST PARAMETERS:

Test	Threshold	Skip	Shuteye	Test Duration	Temperature
Total Viable Count Medium	10	1	30	24 hours	30°C

NOTE: Adjusting the test parameters is not recommended without first consulting NEOGEN Technical Services.

PROTOCOL 2 – STERILITY TESTING (UHT)/PRE INCUBATION USING DIRECT INOCULATION

Sterility testing is often carried out on ultrahigh temperature (UHT) products. It includes a pre-incubation of 48–72 hours (duration dependent on the product and contaminants). Following a pre-incubation, 1 mL or 5 mL of the product is inoculated into a Soleris vial.

1. For pre-incubation, incubate samples at 30°C for 48–72 hours (duration dependent on the product and contaminants).
2. In a sterile environment (under a laminar flow hood, if possible), use isopropyl alcohol to sterilize the top of the UHT carton thoroughly. Allow it to dry.
3. Homogenize and aseptically pipette 1 mL (NF-TVC) or 5 mL (NF-105) of UHT product from carton into the vial that has equilibrated to room temperature.
4. Adjust the pH if required by adding a previously determined volume of acid or base.
5. Cap the vial and gently invert 3 times to mix sample. Slightly loosen the cap to permit air and gas exchange.
6. Insert the vial into the instrument set at 30°C for 24 hours or as indicated by the trainer.

TEST PARAMETERS:

Test	Threshold	Skip	Shuteye	Test Duration	Temperature
Total Viable Count Medium	10	1	30	24 hours	30°C

NOTE: It is not recommended to adjust the test parameters without consulting NEOGEN Technical Services.

PROTOCOL 3 – SPECIFICATION MONITORING (DILUTE TO SPECIFICATION)

Dilutions are made according to the specification and a calculated amount of the appropriate dilution is added to the Soleris vial, dilution scheme guidance is provided below.

1. Allow the Soleris vials to equilibrate to room temperature before use.
2. Complete the dilution required. (E.g. for a 1:10 dilution add 10 g of sample to 90 mL of diluent broth).
3. Inoculate the vial with the appropriate volume of the dilution needed and appropriate quantity of inoculum, no more than 1 mL (NF-TVC) or 5 mL (NF-105) of the sample to be tested.
4. Adjust the pH if required by adding a previously determined volume of acid or base.
5. Cap the vial and gently invert 3 times to mix sample. Slightly loosen the cap to permit air and gas exchange.
6. Insert the vial into the instrument set at 30°C for 24 hours or as indicated by the trainer.

TEST PARAMETERS:

Specification Level (cfu/mL)	Dilution Factor	Dilution Scheme
< 10	0.1	From 1:10 add 1 mL (1000 µl) to vial
< 100	0.01	From 1:100 add 1 mL (1000 µl) to vial
< 200	0.005	From 1:100 add 0.5 mL (500 µl) to vial
< 1000	0.001	From 1:1000 add 1 mL (1000 µl) to vial
< 2000	0.0005	From 1:1000 add 0.5 mL (500 µl) to vial
<10000	0.0001	From 1:10000 add 1 mL (1000 µl) to vial

NOTE: For other specification levels it is recommended to perform the necessary dilutions that allow achieving the required specification level inoculating the vial with between 0.5 mL (500 µl) and 1mL (1000 µl). To inoculate the vial with a lower or higher volume of sample please contact NEOGEN Technical Services for advice.

The presence of at least one cfu of any microorganism in the volume of the sample added to the vial will be detected by the Soleris system and the sample is considered above specification. The absence of detection is considered below specification.

TEST PARAMETERS:

Test	Threshold	Skip	Shuteye	Test Duration	Temperature
Total Viable Count Medium	10	1	30	24 hours	30°C

NOTE: It is not recommended to adjust the test parameters without consulting NEOGEN Technical Services.

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TEST RESULTS

The results of assays are displayed in the main software screen as the software detects a change in the optical units of the sample. This is done without need for an operator. Any sample above specification will be clearly flagged in red. The greater the contamination level, the faster the result, ensuring rapid warning of poor quality raw materials, in-process samples, finished products or surface swabs. Acceptable samples appear in white in the main software screen.

CONFIRMATION (OPTIONAL)

Confirmation is not mandatory for the NF-TVC protocol and is included below for interest only.

Materials required

Plate count Agar (PCA) (NEOGEN Item NCM0010A or equivalent)

Method

From a positive vial, invert to mix and streak 0.1 mL of the broth medium onto a PCA spread plate, or inoculate 1mL in a sterile petri dish and pour approximately 15 mL of PCA and wait until solidified. Incubate at 30°C aerobically for 24-72 hours.

STANDARD REFERENCES FOR TOTAL VIABLE COUNT TESTING

- ISO 4833-1:2013 Horizontal method for the enumeration of microorganisms -- Part 1: Colony count at 30°C by the pour plate method.
- ISO 4833-2:2013 Horizontal method for the enumeration of microorganisms -- Part 2: Colony count at 30°C by the surface plate technique.
- ISO 8553:2004 (IDF 131: 2004) Milk -- Enumeration of microorganisms -- Plate-loop technique at 30°C
- Bacteriological Analytical Manual Chapter 3: Aerobic Plate Count at 35°C

VALIDATIONS

- **AOAC-PTM Validation**

Soleris has been validated and certified by AOAC Research Institute as a Performance Tested Method (certificate No. 071203) for the detection of Total Viable Count in a variety of foods. Please refer to the certificate, available on the AOAC website, for details on the validated protocol.

- **NSF International**

Soleris has been validated in comparison to the USP method for the detection of Total Aerobic Microbial Count in nutraceuticals products. The method has been added to the NSF/ANSI 173

ADDITIONAL VALIDATION INFORMATION

A study was conducted by Neogen's R&D department with 3955 samples of UHT/aseptic packaged products inoculated with heat and peroxide treated sub-lethally injured organisms. It showed a level of detection of 86% after two days pre-incubation and 94.4% after three days. The full validation report is available on request.

PUBLICATIONS

- J AOAC Int. 2013 Mar-Apr;96(2):399-403. Validation of the Soleris NF-TVC method for determination of total viable count in a variety of foods. Mozola M, Gray RL, Feldpausch J, Alles S, McDougal S, Montei C, Sarver R, Steiner B, Cooper C, Rice J.
- J AOAC Int. 2016 Sep;99(5):1331-7. doi: 10.5740/jaoacint.16-0142. Epub 2016 Aug 5. Performance Equivalence and Validation of the Soleris Automated System for Quantitative Microbial Content Testing Using Pure Suspension Cultures. Limberg BJ, Johnstone K, Filloon T, Catrenich C.
- Food Control Volume 103, September 2019, Pages 1-8. Validation protocol for commercial sterility testing methods. Diep B, Moulin J, Bastic-Schmid V, Putallaz T, Gimonet J, DebanValles A, Klijn A.

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LIMITATIONS OF THE METHOD

- Matrices with a negative impact on bacterial growth, such as food containing preservatives, could necessitate an increase of the detection time. Internal validation studies may be required to determine the test duration.
- Certain strains that can be tested with this vial may require a longer time to reach the detection time.
- Certain matrices could have an impact on the detection plug. This may result in an early detection closely following the shuteye period even if the food sample is negative e.g. acidic food samples without pH adjustment could present a matrix impact.

QUALITY CONTROL

Certificate of Analysis (C of A) can be found at https://www.neogen.com/cofa/

CUSTOMER SERVICE

NEOGEN Customer Assistance and Technical Services can be reached by contacting NEOGEN Europe at Tel: +44 (0) 1292 525 600. Training on this product, and all NEOGEN test kits, is available on request.

SDS INFORMATION AVAILABLE

Safety data sheets (SDS) are available on NEOGEN's website at

https://www.neogen.com/solutions/microbiology/soleris-total-viable-count-vial/

WARRANTY

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