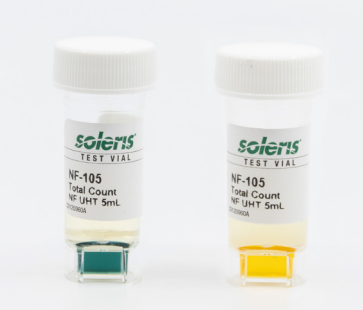
soleris®

Total Viable Count UHT Vial

Product Number: NF-105 (5 mL)



Pictured: NF-105 vial uninoculated/negative (left) and positive vial (right).

For use with the Soleris Microbial Detection System

STORAGE REQUIREMENTS

Store at 2-8°C. Do not freeze.

EXPIRATION DATE

6 months from the date of manufacture.

MATERIALS PROVIDED

- NF-105 includes 1 box of 100 Total Viable Count, UHT vials (5 mL)

VIAL SPECIFICATIONS - NF-105

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

INTENDED USE

The Total Viable Count, UHT vial provides rapid detection of microbial contaminants in Ultra high temperature (UHT) processed and aseptically filled products for the purposes of commercial sterility testing. These include products such as liquid dairy products, baby foods, desserts, sauces, soups, fruit juices and soft drinks.

INTENDED USER

The NF-105 vial is designed for use by quality control personnel and others familiar with commercial sterility testing. Training and support is available through Neogen.

THE MICROORGANISM

NF-105 vials permit the growth and detection of aerobic, mesophilic microorganisms in UHT liquid products. This includes bacteria, yeast and moulds and especially spore forming bacteria which could survive the UHT heat process.

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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 photodiode 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 Next Generation Instrument (SNG-INS32)
- PC pre-loaded with Soleris Fusion software Version 1.8 or later (SNG-COMPUTER-UK)

  or

- Soleris Next Generation Complete System (SNG-32CS)

MATERIALS REQUIRED BUT NOT SUPPLIED FOR TESTING

- Sterile 1 M to 5 M NaOH and/or HCl
- pH meter or pH paper

PH INVESTIGATION AND ADJUSTMENT:

Please refer to the following methods to determine if the matrix has an impact on the pH of the vial. In most cases pH adjustment is not necessary but should be assessed during verification.

Direct matrix pH evaluation protocol

Testing should be carried out on a sample in the vial that will not go through the test procedure to identify the required pH adjustment needed.

- Add up to 5 mL of the sample directly into the vial.
- Cap the vial and gently invert 3 times to mix sample.
- 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).
- The same amount of acid or base used can then be used for the same sample type going forward.

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

GUIDANCE ON TESTING METHODOLOGY

Products that can support the growth of microorganisms (e.g., dairy liquids) can be tested for commercial sterility using Protocol 1 with sample preincubation. Samples that contain preservatives or sub-optimal growth environments (e.g., sauces) can use either an extended sample pre-incubation time, or direct addition as detailed in Protocol 2. Verification of the optimal pre-incubation time can be supported by Neogen Technical Services.

PROTOCOLS

PROTOCOL 1 – ISO 16140-2 VALIDATED COMMERCIAL STERILITY TEST WITH SAMPLE PRE-INCUBATION

- Pre-incubate whole product samples (up to and including 1 L cartons) for 48 hours (up to 72 hours) at 30 °C ± 1 °C.
- Inoculate 5 mL of pre-incubated product into the vial.
- Cap the vial and gently invert three times to mix the sample.
- Insert the vial into the Soleris instrument set at 30 °C and run the commercial sterility program.

TEST PARAMETERS:

Test	Threshold	Skip	Shuteye	Test Duration	Temperature
Commercial Sterility Test	10	1	70	24 hours	30°C

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

NOTE: It is possible to incubate vials in a static air incubator at 30 °C ± 1 °C for a minimum of 24 hours then utilise the Fusion EndPoint reading functionality. This way a single drawer can be used as a reader for a large amount of vials.

PROTOCOL 2 - DIRECT SAMPLE ADDITION

- Add up to 5 mL/g of sample (food matrix or suspensions thereof).
- Cap the vial and gently invert three times to mix the sample.
- Insert the vial into the Soleris instrument set at 30 °C and run the commercial sterility program.

TEST PARAMETERS:

Test	Threshold	Skip	Shuteye	Test Duration	Temperature
Commercial Sterility Test	10	1	70	24 hours	30°C

NOTE: Shuteye period can be reduced if no matrix interference is observed. Consult Neogen Technical Services for further guidance.

TEST RESULTS

The results of assays are displayed by the Fusion software as it detects a change in the optical reading of the vial plug. This is automated and occurs in real time. Any test that detects growing microorganisms will be clearly flagged in red. The greater the microbial load, the faster the result, ensuring rapid warning of contamination. Negative samples do not trigger a colour change in the software and run to the end of the designated test time.

CONFIRMATION (OPTIONAL)

Confirmation is not mandatory but possible by subculture direct from the vial and/or original sample sample container.

Materials required

Plate Count Agar (PCA) (Neogen Item NCM0010 or equivalent)

Method

From a positive NF-105 vial, invert to mix and streak 0.1 mL of the broth medium onto a Plate Count Agar spread plate. Incubate at 30 °C aerobically for up to 72 hours. The same direct streaking process can be applied to original sample container to confirm microbial contamination.

VERIFICATION

Method verification should be done following the protocols described in ISO 16140:3:2021. The user laboratory shall select one of the three protocols described in chapter 5, 'Qualitative methods- Technical protocol for verification'.

STANDARD REFERENCES

- Codex Code of Hygienic practice for milk and milk products (CAC/RCP 57-2004). Annex B Microbioicidal control measures Section 2.2 process management for UHT treatment using ISO 4833-1:2013 for the plate count at 30 °C
- Council Directive 92/46/EEC of health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products. Official Journal L 268, 14/09/1992 P. 0001 - 0032
- ISO 4833-2:2013Microbiology of the food chain — Horizontal method for the enumeration of microorganisms — Part 2: Colony count at 30 °C by the surface plating technique
- Diep, Benjamin, et al. "Validation protocol for commercial sterility testing methods." Food control 103 (2019): 1-8
- Mozola, Mark, et al. "Validation of the Soleris® NF-TVC method for determination of total viable count in a variety of foods." Journal of AOAC International 96.2 (2013): 399-403.

VALIDATIONS

MICROVAL (ISO 16140-2:2016)

The Soleris NF-105 commercial sterility protocol has been certified by MicroVal as an alternative to the reference standard Codex Code of Hygienic practice for milk and milk products (CAC/RCP 57-2004). Annex B Microbioicidal control measures Section 2.2 process management for UHT treatment using ISO 4833-1:2013 for the plate count at 30 °C Refer to MicroVal 2021LR100 for more information.

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LIMITATIONS OF THE METHOD

- Matrices with a negative impact on microbial growth, such as food containing preservatives, may require an extension to the pre-incubation time and/or test duration. Consult Neogen Technical Services for guidance.
- 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.

For all cases above an adjustment of the protocol and/or the parameters would be required, please contact Neogen Technical Services for additional information.

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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