CompactDry™ TC

Simple and Easy Dry Medium for Total Viable Count

Background

It is important to detect and measure total viable microorganisms in foodstuffs and the food production environment to monitor the degree of cleanliness and sanitary safety. The standard pour plate method is widely used to determine microbial count. However, the pour plate method is time consuming and labour intensive. To save operator time in performing microbial count without difficulty, Shimadzu Diagnostics Corporation developed CompactDry™ plates based on a new technology applicable to the food industry.

Features and Benefits

1. A compact media plate: Only requires a small space for storage and incubation.
2. Ready to use: No need to prepare culture medium, therefore reducing both waste and equipment required. It is also well adapted for emergency and field testing.
3. The sample diffuses passively and evenly across the dehydrated media sheet, rehydrating the dry medium into a gel within seconds.
4. 24-month shelf life at room temperature: Easy to store.
5. Simple colony observation by redox colour indicator: Easy to interpret and isolated colonies can be subculture individually.
6. Good correlation with the pour plate method: Maintains data comparability.

Intended Use

CompactDry™ TC is intended for the enumeration of total viable count in food and related samples.

Certification by AOAC

CompactDry™ TC has been compared to the AOAC *Official Method* SM **966.23** and certified by the AOAC Research Institute *Performance Tested Methods*SM Program (Certificate No. 010404) for enumeration of total viable count in raw meat (raw ground beef, raw ground pork, raw pork, raw lamb and veal). A matrix extension comparing CompactDry™ TC to ISO 4833-1: 2013 for cooked chicken, fresh pre-washed bagged shredded iceberg lettuce, frozen cod filets, instant non-fat dry milk, and pasteurized 2% milk was also approved in 2015.

A matrix extension to raw chicken breast with enumeration at 24h and 48h and a modification for raw ground beef for enumeration at 24h compared to FSIS MLG Chapter 3.02 were approved in 2020.

Certification NF VALIDATION by AFNOR Certification

The CompactDry™ TC method has been certified NF VALIDATION as an alternative analytical method for the enumeration of total viable organism in all human food products (by performing validation assays in a broad range of foods) and industrial food production environmental samples.

This validation has been obtained by comparison to the reference method described in the international standard EN ISO 4833-1: 2013 and the NF VALIDATION certification according to EN ISO 16140-2: 2016 protocol.

For more information about the period of validity of the NF VALIDATION certification, please refer to certificate N° SDC 42/03–12/24 available on the website http://nf-validation.afnor.org/en and/or on request from Shimadzu Diagnostics Corporation.

Certification by MicroVal/NordVal

CompactDry™ TC has been validated in accordance with EN ISO 16140-2: 2016 and the MicroVal Rules and Certification Scheme version 9.1 and revealed to be at least equivalent to the reference method ISO 4833-1: 2013. Validation has been performed on a broad range of foods (dairy products, fishery products, fresh and processed produce, meat and meat products, poultry and poultry products), pet food and environmental samples.

The validation report is available on the MicroVal website: www.microval.org

Test Kit Components

1. CompactDry™ TC Plates

Additional reagents and materials required but not provided

1. Butterfield's phosphate-buffered diluent (BPBD) – Prepare according to AOAC 966.23
2. Maximum Recovery Diluent (MRD) – Prepare according to ISO 4833-1: 2013 (AOAC)
3. Buffered Peptone Water (BPW) – Prepare according to ISO 6887 (NF VALIDATION)
4. Filtered Stomacher™ bags

Apparatus

1. Blender or Stomacher™ or equivalent for homogenizing sample
2. Sterile Pipette – 1 mL
3. Incubator

Operating Procedure

Sample preparation

For preparations of initial suspensions, follow instructions of EN ISO 6887 standards or ISO 18593 for environmental samples.

1. Sample preparation: Use appropriate sterile diluents: For further information, see section "**Specific Instructions for Validated Methods**".
2. Blend or homogenize sample (see section "**Specific Instructions for Validated Methods**").
3. If sample has a low or high pH, adjust the pH to 6.8 – 7.2 for an optimal growth and recovery of microorganisms.

General Instructions for use CompactDry™ TC

Also refer to specific instructions for AOAC, NF validation, MicroVal and NordVal certifications

1. Open the aluminium pouch and take out a set of 4 plates and detach the number of plates required.
2. A set of four connected plates can be used for serial dilution of the same sample.
3. Enumeration range of CompactDry™ TC is 1–300 CFU/plate. Sample should be diluted in buffer to obtain a concentration level of less than 300 CFU/plate.
4. Remove cap from plate, pipette 1 mL of sample (diluted if necessary) in the middle of the dry sheet and replace the lid. The sample will diffuse passively and evenly across the dehydrated media sheet, rehydrating the dry medium into a gel within seconds.
5. Write the appropriate sample information in the label section.
6. Turn the plate over (lid down) and incubate for the appropriate time and temperature. (See specific instructions for validated methods**).** CompactDry™ plates are stackable up to 6 plates for incubation (NF validation).
7. Following incubation, count the number of coloured/colourless microbial colonies from the back of the plate. White paper placed under the plate can make colony counting easier.

Interpretation

1. CompactDry™ TC is a non-selective medium with the redox indicator 2,3,5-Triphenyl Tetrazolium Chloride (TTC). Colonies grown on CompactDry™ TC are almost all red in colour. Calculate the number of microorganisms present in the test sample according to ISO 7218 for one CompactDry™ TC plate per dilution.
2. Refer to EN ISO 7218 for inoculation, calculation and recording results.
3. Some microorganisms may not reduce TTC and colonies may develop on CompactDry™ TC which are not red. All colonies (coloured and none coloured) must be counted.

Specific Instructions for Validated Methods

AOAC® Official Methods℠ 966.23

Scope of validation: All human food products, pet food and industrial environmental samples.

Sampe preparation: Prepare appropriate diluent: Butterfield's phosphate-buffered diluent (BPBD) for raw meat products or MRD for other matrices. Autoclave to sterilise.

Viable count in solid foodstuffs:

- For raw meat, weigh 50 g of sample and add 450 mL BPBD to the sample. Homogenize with a blender for 2 min ± 15s.
- For cooked chicken, fresh lettuce or frozen fish, weigh 10g of sample and add 90 mL MRD. Homogenize by stomacher for 1 min ±15s.
- For milk powder, weigh 10g of sample and add 90 mL of MRD pre-warmed to 45°C ± 1°C. Slowly swirl and shake until sample is in suspension.

Viable count in liquid foodstuffs for pasteurized milk, either do not dilute or if viable count is > 300 CFU/plate, dilute 1 mL in 9 mL MRD and vortex to mix.

Incubate CompactDry™ TC plates at: 35 ± 1°C (raw meat products) or 30 ± 1°C (all other matrices) for 48 ± 3 h.

Follow guidelines provided in the **Interpretation** section of this document.

NF Validation by AFNOR Certification

The **NF Validation** certified method (SDC 42/03–12/24) is in compliance with ISO 16140-2: 2016 in comparison to EN ISO 4833-1: 2013

Use the following instructions in addition to the General Instructions for Use:

Scope of the validation: All human food products, pet food and industrial environmental samples.

Sample Preparation: Diluent (e.g.: BPW) is used for all liquid and solid food matrices. If required, dilute the sample 10-fold (according to the ISO 6887).

Environmental sample: Viable count using a swab pre-immersed in 1mL of BPW (only included in the NF VALIDATION); is used without further dilution or serially diluted in BPW if required. It is recommended to use CompactDry Swab BPW (450004-BPW-0500) available as an optional kit.

Incubation: 30°C ± 1°C for 48 h ± 3 h.

Interpretation: Calculate the number of microorganisms present in the test sample according to ISO 7218 for one CompactDry™ TC plate per dilution. Estimates are outside of the scope of the NF Validation certification

MicroVal (2007LR01) /NordVal (No: 033) Certifications: Compliant with the ISO 16140-2: 2016 in comparison with the reference method ISO 4833-1: 2013

Scope of validation: Broad range of foods (five categories), pet food and environmental samples.

Sample Preparation: Samples diluted in an appropriate diluent according to ISO 6887 and homogenised in a stomacher.

Incubation: 30 ± 1°C for 48 ± 3h.

Interpretation: Following incubation, red and otherwise coloured colonies were counted, and the CFU/g was calculated for each sample, according to ISO 7218.

Precaution for use

1. Comply with Good Laboratory Practices (refer to EN ISO 7218 standard).
2. Do not use CompactDry™ TC for human or animal diagnostics.
3. To avoid microbial contamination, do not touch the surface of the medium sheet before or after inoculation.
4. During incubation, keep lid tightly closed to avoid dehydration.
5. Use of filtered stomacher bags is recommended to eliminate risks of carryover of foodstuffs onto the surface of the medium.

6. If more than 10^4 CFU/mL are inoculated onto a plate, no distinguishable coloured colonies will form and the entire plate will become homogeneously coloured.
7. If the nature of the sample could affect the reaction with the chromogenic medium, it may require dilution, pH adjustment or other. This may also include high viscosity samples, coloured sample, and sample which could react with the redox indicator due to high or low pH.

Warning and precautions for use

1. General precautions

1. Read and follow warnings and precautions for use described in the package insert and/or label.
2. Do not use the product after its expiration date. Quality of the product is not guaranteed after shelf-life date is expired.
3. Do not use CompactDry™ TC if the plate is contaminated, it has become artificially discoloured or has a damaged container.
4. Use plates as soon as possible after opening. Return any unused plates to the aluminium pouch, seal with tape to avoid light and moisture and store at RT.
5. CompactDry™ TC is sensitive to light, which will affect the colour development of colonies.
6. Replace cap tightly after inoculation to avoid dehydration of gelled medium.

2. Safety Precautions

1. If medium or reagent comes into contact with eyes or mouth, immediately wash with water and consult a physician.
2. Manipulation of microorganisms involves a risk of laboratory acquired infection. Manipulation should be carried out under the supervision of trained laboratory personnel with biohazard protection measures.
3. Treat any laboratory equipment, or medium that comes into contact with the sample, as infectious and sterilize appropriately.

3. Precautions for waste disposal

Sterilize any medium, reagent or materials by autoclaving after use, and then dispose as industrial waste according to local laws and regulations for disposal of such material.

4. User Responsibility

1. It is the user's responsibility in selecting any test method to evaluate a sufficient number of samples with particular foods and microbial challenges to satisfy the user that the chosen test method meets the user's criteria.
2. It is the user's responsibility to determine that any test methods and results meet its customers' or suppliers' requirements. The user must train its personnel in proper testing techniques.
3. It is the user's responsibility to validate the performance of this method for use with any non-certified matrix.

5. Limitation of Warranties

CompactDry™ plates are manufactured at an ISO 9001:2015 facility.
If any CompactDry™ plate is proven to be defective by fault of the manufacturer, or its authorized distributors, they may replace or, at their discretion, refund the purchase price of any plate.

Storage and Shelf life

Storage: Room temperature (1 – 30 °C).
Shelf life: Twenty-four (24) months after manufacturing.
Expiration date is printed on outer box label and aluminium pouch label.

Package

CompactDry™ TC 100 plates Code HS8771

References

1. ISO 4833-1:2013. Microbiology of the food chain — Horizontal method for the enumeration of microorganisms - Part 1: Colony count at 30 °C by the pour plate technique.
2. ISO 18593:2018. Microbiology of the food chain — Horizontal methods for surface sampling.
3. ISO 16140-2:2016. Microbiology of the food chain - Method validation - Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method
4. ISO 6887 (Part 1 to 5). Microbiology of the food chain — Preparation of test samples, initial suspension and decimal dilutions for microbiological examination
5. ISO 7218. Microbiology of the food chain - General requirements and guidance for microbiological examinations.

Tracking version

Date	Action	Name
July 2023	Issue	SDE-IFU-TC-2023-V01
February 2024	Revision	SDE-IFU-TC-2024-V02
October 2024	Revision	SDE-IFU-TC-2024-V03
November 2024	Revision	SDE-IFU-TC-2024-V04
December 2024	Revision	SDE-IFU-TC-2024-V05

Further information
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ALTERNATIVE ANALYTICAL METHODS FOR AGRIBUSINESS

http://nf-validation.afnor.org/en

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