CompactDry™ X-SA

Simple and Easy Dry Medium for *Staphylococcus aureus*

Background

It is important to detect and measure the bacterial contamination 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.
CompactDry™ X-SA is a medium to detect *S. aureus* by the combination of selective agents and chromogenic substrates.

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. 21-month shelf life at room temperature: Easy to store.
5. Clear-cut colour development: *S. aureus* forms light blue/blue colonies. Easy to interpret. Isolated colonies can be subcultured individually.
6. Good correlation with the pour plate method: Maintains data comparability.

Intended Use

CompactDry™ X-SA is intended for use for the isolation and enumeration of *Staphylococcus aureus* only (and not all coagulase-positive *Staphylococci*) in food and related samples.

Certification by AOAC

CompactDry™ X-SA has been compared to ISO 6888-1 (1999) and certified by the AOAC Research Institute Performance Tested Methods℠ (PTM) Program (Certificate No. 081001) for enumeration of *Staphylococcus aureus* in frozen prawns, cooked ham, unpasteurized cow's milk, cream pastries & chilled fresh pasta.

Certification NF VALIDATION by AFNOR Certification

The CompactDry™ X-SA method has been certified NF VALIDATION as an alternative analysis method for the enumeration of *Staphylococcus aureus* in all human food products (by performing validation assays in a broad range of foods) and industrial production environmental samples.
This validation has been obtained by comparison to the reference method described in the international standard EN ISO 6888-2: 2021 and its amendment 1 (2023), and the NF VALIDATION certification is according to EN ISO 16140-2:2016 protocol.
For more information about the end of validity of the NF VALIDATION certification, please refer to the certificate N°SDC 42/04-12/24 available on the website http://nf-validation.afnor.org/en and/or on request asking Shimadzu Diagnostics Corporation.

Certification by MicroVal/NordVal

CompactDry™ X-SA has been validated in accordance with EN ISO 16140-2: and is at least equivalent to the reference method ISO 6888-1: 2021.
Scope of validation: Broad range of foods, environmental samples, pet food and animal feed. Validation has been performed on a broad range of foods (dairy products, fish products, fresh and processed produce, meat and meat products, poultry and poultry products), pet food and environmental samples. Validation report is available on the MicroVal website: www.microval.org

Test Kit Components

1. CompactDry™ X-SA Plates

Additional reagents and materials required but not provided

1. Appropriate diluents (see section: Specific Instructions for Validated Methods)
2. 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™ X-SA

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™ X-SA is 1–150 CFU/plate. Sample should be diluted in buffer to obtain a concentration level of less than 150 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 at 37± 1 °C for 24 ± 2 hours, count the number of light blue/blue colonies microbial colonies from the back of the plate. White paper placed under the plate can make colony counting easier.

Interpretation

Staphylococcus aureus forms light blue/blue colonies of 1~2 mm in diameter. Refer to EN ISO 7218 standard for calculation and recording results.

Precaution for interpretation

1. Some bacteria other than *S. aureus* may also grow and form white and/or red purple colonies on this plate, only light blue/blue colonies should be counted.
2. Bacteria other than *S. aureus*, and some of *Bacillus* species may grow and form light blue/blue colonies. It is easy to differentiate them from *S. aureus*, because they form relatively large, matt and flat colonies.

Specific Instructions for Validated Methods

AOAC Research Institute Performance Tested Methods℠ (PTM) Program

Scope of validation: Food products.
Sampe preparation: Prepare appropriate diluent according to ISO 6887, Maximum Recovery Diluent (MRD) was used for AOAC PTM certification. Autoclave to sterilise.
For solid foodstuffs: Weigh 10g of solid sample and add 90mL diluent (MRD for AOAC). Homogenise with a blender
For water or liquid foodstuffs: Pipette 1mL of liquid sample (to be diluted if necessary) in the middle of dry sheet of CompactDry™ X-SA.
Incubate CompactDry™ X-SA plates at: 37 ± 1°C for 24 ± 2 h.
Follow guidelines provided in **Interpretation** section of this document.

NF Validation by AFNOR Certification

NF Validation certified method (42/04-12/24) in compliance with ISO 16140-2: 2016 in comparison to ISO 6888-2 (2021) and its amendment 1 (2023),
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 Part 1 to 5).
For solid foodstuffs: Weigh a portion* of sample and add 9 volumes of BPW to the sample. Homogenise with a blender.
*In the scope of NF VALIDATION, test portions weighing more than 25g have not been tested.
For water or liquid foodstuffs: Pipette 1mL of liquid sample (diluted if necessary) in the middle of dry sheet of CompactDry™ X-SA.
For swab test sample: Bacterial count using a swab pre-immersed in 1mL of BPW (only included in the NF VALIDATION) can be 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: 37°C ± 1°C for 24 ± 2 h.
Interpretation: Calculate the number of microorganisms present in the test sample according to ISO 7218 for one CompactDry™ X-SA plate per dilution. Estimates are outside of the scope of the NF Validation certification

MicroVal/NordVal Certifications: Complaint with ISO 6888-1: 2021
Scope of the validation: Broad range of foods, environmental samples, pet food and animal feed.
Sample Preparation: Samples were diluted in an appropriate diluent according to ISO 6887 and homogenised with a stomacher.
Incubation: 37°C ± 1°C for 24 ± 2h
Interpretation: Follow guidelines provided in Interpretation section of this document.

Precaution for use

1. Comply with Good Laboratory Practices (refer to EN ISO 7218 standard).
2. Do not use CompactDry™ X-SA 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. Detection limit of CompactDry™ X-SA is between 1 – 150 CFU/plate. Sample should be diluted by the appropriate diluent to the level of concentration of less than 150 CFU/plate.
7. 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.
8. 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 its shelf-life date is expired.
3. Do not use CompactDry™ X-SA if the plate is contaminated, it has become artificially is 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™ X-SA is sensitive to light, light exposure 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-one (21) months after manufacturing.
Expiration date is printed on outer box label and aluminium pouch label.

Package

CompactDry™ X-SA 100 plates Code HS9621

References

1. ISO 6888-1: 2021 Microbiology of food and animal feeding stuffs - Horizontal method for the enumeration of coagulase - positive staphylococci (*Staphylococcus aureus* and other species) - Part 1 - Technique using Baird-Parker agar medium.
2. ISO 6888-2:2021/A1:2023 Microbiology of the food chain — Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species).
3. ISO 18593:2018 Microbiology of the food chain — Horizontal methods for surface sampling.
4. 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
5. ISO 6887 (Part 1 to 5). Microbiology of the food chain — Preparation of test samples, initial suspension and decimal dilutions for microbiological examination
6. ISO 7218. Microbiology of the food chain - General requirements and guidance for microbiological examinations.

Tracking version

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

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BY AFNOR CERTIFICATION NF VALIDATION EN ISO 16140

SDC 42/04-12/24

ALTERNATIVE ANALYTICAL METHODS FOR AGRIBUSINESS

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

Manufactured by

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