

CompactDryTM YMR

| Cat. no. 54084 | CompactDry [™] YMR, 60x75mm Tray with 10x60mm Well | 240 trays/box |
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INTENDED USE

Hardy Diagnostics CompactDryTM YMR is a rapid, ready-to-use test method recommended for enumeration of yeast and mold growth in raw materials, finished products, or on environmental surfaces pertaining to food and other related industries

This product is not intended to be used for the diagnosis of human disease.

SUMMARY

Fungi (yeast and mold) are a large, diverse group of organisms that can live in a wide range of environments. Most fungi are obligate aerobes and can grow in broad pH and temperature ranges. This makes them capable of thriving in many types of foods, causing various degrees of food spoilage. Invasion and growth may occur on virtually any type of food or plant if environmental conditions are not limiting. Commodities such as corn, small grains, legumes, nuts, fleshy fruits, and cannabis can be invaded prior to harvesting as well as during storage.

Yeasts and molds are distributed widely in decaying plant materials, soil, and air. Their presence on unprocessed plant and animal foodstuffs is almost assured by harvesting, handling, distribution, and storage practices used in food or cannabis industries, and inadequate preservation of these commodities can result in mycological spoilage. Detection and enumeration of yeasts and molds in food or cannabis is an integral part of any good quality assurance program and can reflect the effectiveness of sanitation practices, processing schemes, and distribution conditions.

CompactDryTM YMR is a ready-to-use chromogenic medium for performing yeast and mold counts that contains dehydrated culture media and a cold water-soluble gelling agent in a non-woven cloth matrix. The medium is instantly hydrated when inoculated with a sample, and capillary action diffuses the sample evenly over the matrix to form a gel within seconds. CompactDryTM YMR contains the chromogenic substrate, X-Phos that yields a blue-green reaction when utilized by most yeast species.

CompactDryTM YMR is AOAC validated (PTM 092002) and works similarly to the CompactDryTM YM (Cat.No. 54083), another AOAC validated (PTM 100401) product, but with a shorter read time. The ready-to-use trays save space and greatly reduce the time needed to perform microbiological testing. Compared to other commonly used culture systems, CompactDryTM has a longer shelf life, can be stored at room temperature, does not require manual sample spreading, is rigid, stackable and easy to label, and allows for direct colony picking for further subculture.

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification.

CERTIFICATION BY AOAC

The CompactDry YMR has been compared to ISO 21527-1:2008 and certified by the AOAC Research Institute *Performance Tested Methods*SM (PTM) Program (PTM 092002) for enumeration of yeasts and molds in cooked

prawns, deli vegetable salad, tuna pâté, fermented strawberry yogurt drink, spinach and ricotta quiche, egg custard tarts, fruit and vegetable smoothie, cream cheese, egg salad sandwiches, and deli pasta salad. A PTM Matrix Extension was completed to include enumeration of yeasts and molds in dried cannabis flower. MicroVal certification was achieved in compliance with ISO 16140-2:2016 and comparison to ISO 21527-1:2008 (Certificate No. 2016LR61).

FORMULA

CompactDryTM YMR contains dehydrated Potato Dextrose Agar, a gelling agent, and the chromogenic substrate 5-bromo-6-chloro-3-indoxylphosphate (X-Phos) to assist in differentiating yeast colonies.

Final pH 5.5 +/- 0.3 at 25°C.

STORAGE AND SHELF LIFE

Storage: Upon receipt, store at 1-30°C. Media should not be used if there are any signs of deterioration, contamination, or if the expiration date has passed. If foil pouch is opened and not all plates are used, return remaining plates to pouch and reseal until next use to avoid light and moisture. Opened packages should be used as soon as possible. Shelf life is 24 months after manufacturing.

PRECAUTIONS

General precautions

1) Read and follow the warnings and directions for use described in the package insert and/or label precisely.

2) Do not use the product after its expiration date. Quality of the product is not guaranteed after its shelf life.

3) Do not use product that contains any foreign materials, is discolored or dehydrated, or has a damaged container.

4) Use plates as soon as possible after opening. Any unused plates should be returned to the aluminum bag and sealed with tape to avoid light and moisture.

5) Cap tightly after inoculation to avoid dehydration of gelled medium.

Safety Precautions

1) Immediately wash with water if medium or reagent comes into contact with eyes or mouth. Consult a physician.

2) Manipulations with microorganisms involve certain risks of laboratory-acquired infections. Practice manipulations under the supervision of trained laboratory personnel with biohazard protection measures.

3) Treat laboratory equipment or medium that comes in contact with the specimen as infectious and sterilize appropriately.

Precautions for disposal of waste

Sterilize any medium, reagent and materials by autoclaving or boiling after use, and then dispose as industrial waste according to local laws and regulations.

PROCEDURE

Sample Preparation

- 1) Prepare Maximum Recovery Diluent (MRD) or Butterfield's Phosphate Buffered Diluent (BPBD). Autoclave for sterilization.
- 2) Viable count in solid foodstuffs Weigh 10 g of sample into a sterile filtered stomacher bag. Add 90 mL MRD. Homogenize in a stomacher for 1 min ± 10 s. Make 10-fold serial dilutions by diluting 10 mL homogenate in 90 mL MRD. Mix by shaking
- 3) Viable count in cannabis flower Weigh 10 g of sample into a sterile filtered stomacher bag. Add 90 mL Butterfield's Phosphate Buffer. Homogenize in a stomacher for 1 min ± 10 s. Make 10-fold serial dilutions by diluting 10 mL homogenate in 90 mL Butterfield's Phosphate Buffer. Mix by shaking
- 4) Viable count in liquid foodstuffs Weigh 10 g of sample into a sterile stomacher bag and add 90 mL MRD. Homogenize in a stomacher for

1 min \pm 10 s. Make 10-fold serial dilutions by diluting 10 mL homogenate in 90 mL MRD. Mix by shaking.

 Viable count in swab test sample (not included in AOAC validation) Use wiping solution (without dilution or diluted in MRD if necessary) obtained from the cotton swab.

Directions for CompactDryTM **YMR**

- 1) Open aluminum bag, and remove a set of 4 plates.
- 2) Detach necessary number of plate(s) from a set of four by bending up and down while pressing the lid. Use a connected set of four plates when serial dilution measuring is intended.
- 3) Remove the cap from the plate, pipette 1 mL of sample (to be diluted further if necessary) in the middle of the dry sheet, and replace cap. Sample diffuses automatically and evenly over the entire sheet (total medium of 20 cm²) to transform it into gel within seconds.
- 4) Write the appropriate information on the memorandum section. Invert the capped plate and place in incubator at $25 \pm 1^{\circ}$ C for 72 ± 3 hours.
- 5) From backside of the plate, count the number of any colored colonies (usually green/blue) and "cottony" colonies in the medium. White paper placed under the plate can make colony counting easier. For large numbers of colonies, use the grids carved on the backside consisting of 1 cm x 1 cm, or 0.5 cm x 0.5 cm, at the four corners.
- 6) The enumeration range of the CompactDry[™] YMR is 1 150 cfu/plate. Dilute samples further in the appropriate diluent as necessary to achieve a concentration level in the countable range.

Additional recommendations:

It is recommended to use a stomacher and filter homogenized sample to eliminate carryover of tiny particles of food stuff onto the surface of the medium.

Additional procedures:

For Making 1:10 Serial Dilutions:

- 1. Using a sterile pipet or scoop, aliquot 10mL or 10gm of test sample to a 90mL pre-filled Dilu-Lok II[™] dilution vial to yield a 1:10 diution. Mix thoroughly.
- 2. From the 1:10 dilution vial in step 1, use a fresh sterile pipet and aliquot 10mL from this dilution vial into a second 90mL pre-filled Dilu-Lok IITM vial to yield a 1:100 dilution from the original sample. Mix thoroughly.
- 3. Continue aliquoting 10mL dilutions into 90mL pre-filled Dilu-Lok IITM vials until the desired test concentration of test sample is achieved. Each subsequent dilution increases by a factor of 10. A separate sterile pipet should be used with each dilution.

For Making 1:100 Serial Dilutions:

- 1. Using a sterile pipet or scoop, aliquot 1mL or 1gm of test sample to a 99mL pre-filled Dilu-Lok II[™] dilution vial to yield a 1:100 diution. Mix thoroughly.
- From the 1:100 dilution vial in step 1, use a fresh sterile pipet and aliquot 1mL from this dilution vial into a second 99mL pre-filled Dilu-Lok IITM vial to yield a 1:10,000 dilution from the original sample. Mix thoroughly.
- 3. Continue aliquoting 1mL dilutions into 99mL pre-filled Dilu-Lok IITM vials until the desired test concentration of test sample is achieved. Each subsequent dilution increases by a factor of 100. A separate sterile pipet should be used with each dilution

INTERPRETATION OF RESULTS

Counting colonies may be difficult against a dark background. For best results, count colonies using the Hardy Diagnostics WizardTM CompactDryTM plate reader (Cat. no. CDR1) (not evaluated by the AOAC) or with the tray held against a white or illuminated background such as with the Scan®100 colony counter (Cat. no. 435000) (not evaluated by the AOAC).

If using a light box, the molded grid lines or colonies maybe difficult to view due to excessive brightness. Diffuse the light using a sheet of white, gridded (1cm x 1cm) paper underneath the tray to facilitate colony counting.

A dilution may be needed when the sample has a dark color.

Blue colored colonies indicate yeasts. Molds form cottony colonies with characteristic colors. While most colonies are some shade of green/blue, any colored colony should be counted. In addition, mold colonies may have a diffuse or cottony appearance.

The full plate size is 20 cm². The backside contains carved grids of 1 cm \times 1 cm and 0.5 cm x 0.5 cm to make colony counting easier. If large numbers of colonies are present on the medium, the total viable count can be obtained by averaging the number of colonies per large grid (1 cm \times 1 cm), counted from several grids, and multiplying by 20. Alternatively, when large numbers of colonies are present, the total viable count can be obtained by averaging the number of colonies per small grid (0.5 cm \times 0.5 cm) and multiplying by 80.

LIMITATIONS

If more than 10⁴ cfu/mL were inoculated onto a CompactDry YMR plate, no distinguishable colored colonies will form and the entire plate may become colored. During inoculation, do not touch the surface of medium and be careful to avoid any contamination by airborne microorganisms.

During exclusivity testing, *Klebsiella pneumoniae* and *Pseudomonas fluorescens* showed growth on the CompactDryTM YMR medium after 72 h at $25\pm1^{\circ}$ C when inoculated at a high level (>10⁸ CFU/mL). *Klebsiella pneumoniae* grew weakly with less than 10 small blue colonies after 72 hours of incubation. *Pseudomonas fluorescens* showed no distinct colonies, but the background of the plate turned green, indicating a lawn of growth.

MATERIALS REQUIRED BUT NOT PROVIDED

Butterfield's phosphate-buffered diluent (BPBD)

Maximum recovery diluent (MRD) - Prepare according to ISO 21527-1:2008.

Sterile Filtered Stomacher bags

Blender, StomacherTM, or equivalent for homogenizing sample

Standard microbiological supplies and equipment such as loops, swabs such as EnviroTransTM, applicator sticks, scoops, WizardTM CompactDryTM plate reader (Cat. no.CDR1), Scan® 100 colony counter (Cat. no. 435000) (not evaluated by the AOAC), incinerators, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

End users should anticipate the following typical performance characteristics when testing with CompactDryTM.

| Test Organisms | Inoculation | Incubation | | | Pogulto |
|---|-------------|------------|-------------|------------|-------------------------------------|
| Test Organisms | Method* | Time | Temperature | Atmosphere | Kesuits |
| Candida glabrata JCM® 3699 | J | 48-72 hrs | 25-30°C | Aerobic | Growth; light bluish green colonies |
| Candida albicans ATCC® 10231 | J | 48-72 hrs | 25-30°C | Aerobic | Growth; light yellow green colonies |
| Aspergillus brasiliensis ATCC® 16404 | J | 48-72 hrs | 25-30°C | Aerobic | Growth; blue colonies |
| Bacillus subtilis ATCC ® 6633 | J | 48-72 hrs | 25-30°C | Aerobic | Inhibited |
| Escherichia coli ATCC® 8739 | J | 48-72 hrs | 25-30°C | Aerobic | Inhibited |

* Refer to the document "Inoculation Procedures for Media QC" for more information.

PHYSICAL APPEARANCE

CompactDry[™] YMR should appear dry, free of particles and light yellow in color.

ATCC is a registered trademark of the American Type Culture Collection. CompactDryTM is a trademark of Shimadzu Diagnostics Corporation. Scan is a registered trademark of Interscience for Microbiology.

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Manufactured for and distributed by:

HARDY DIAGNOSTICS

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 $\label{eq:construction} Distribution \ Centers: \\ California \cdot Washington \cdot Utah \cdot Arizona \cdot Texas \cdot Ohio \cdot Florida \cdot New \ York \cdot North \ Carolina$

The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

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