** コンパクトドライ™TC

* * ------ 開発の経緯および特徴 ----

食品の安全性を確保する上で、食品や環境中の微生物数を測定することは極めて 重要です。従来より行われている汚染指標菌の混釈培養検査は培地の準備や試料の 混釈操作に多くの労力と経験を必要としていました。

コンパクトドライ[™]TCは、このような負担を軽減し、誰でも、どこでも、簡便に 混釈培養が行えるよう開発した培地で、試料液を加えるだけの操作で菌数検査が実 施できます。

「特 徴]

- 1) コンパクトなサイズなので場所をとりません。
- 2) 培地調製の必要がありません。
- 3)接種した試料は自然に均一に拡散します。
- 4) 室温で保存可能です。
- 5) コロニーの発色が明りょうで、釣菌も容易にできます。
- 6) 従来の混釈培養法のデータと整合性がとれます。

—— 操 作 法 ——

[試料の調製、接種方法]

1. 固形食品材料の菌数測定

材料に緩衝液を添加し、ストマッカーで均質化します。試料液 1 mL (必要に応じて希釈する)を取り、本品に接種します。

2. 水や液状食品の菌数測定

試料液1mL(必要に応じて希釈する)をそのまま本品に接種します。

**3. ふき取り材料の菌数測定

綿棒などで食品や環境材料をふき取ったふき取り液 $1\,\mathrm{mL}$ (必要に応じて希釈する)を本品に接種します。

簡易ふき取りキット (BPW) ガンマ線滅菌 (コード06537) 又は簡易ふき取りキット (PBS) CCガンマ線滅菌 (コード06538) を使用すると便利です。

[使用法]

- 1)アルミ袋を開封し、4連のプレートを取り出します。
- 2)検査に必要な枚数のプレートを折り曲げて切り離します。段階希釈した試料液を接種するときは切り離さずそのまま使用すると便利です。
- 3) プレートのフタを開け、シートの中央部に試料液 1 mLを接種します。試料液は シート全体(培地面積は20cm²)に均一に広がりゲル化します。
- *4)フタをした後、倒置しフラン器に入れて、35±1℃で48±3時間培養します。
- 5) 発色したコロニーを裏面からカウントします。下に白い紙などを置いてカウントするとコロニーが見やすくなります。

----- 操作上の留意事項 ----

- 1) 試料の接種に際しては、落下菌による汚染や培地面に手指が触れるなどの汚染に注意してください。
- 2) 培養中の乾燥を防ぐため、フタはしっかりと閉めてください。
- 3)食材片の持ち込みによる影響を防ぐため、なるべくフィルター付きストマッカー袋を使用してください。
- 4) 試料は1 プレートあたり300cfu以下になるように緩衝液などで希釈してから接種します。滅菌希釈液 II(コード01553)を使用すると便利です。
- 5) 1プレートあたり10^tcfu以上の菌が接種されるとコロニーが形成されないため発 色コロニーが現れず、シート全体が着色したようになります。
- 6) 食品自体が培地の反応に影響を与えるものは、緩衝液などで希釈する等、その 原因を取り除いてから接種してください。

例:粘度の高いもの、濃く着色したもの、酸化還元指示薬と反応するもの、pH が極端に高いかまたは低いもの。

———判定法——

[判定法]

非選択性の培地に酸化還元指示薬テトラゾリウム塩(2,3,5-Triphenyl Tetrazolium Chloride 以下TTC)が含まれており、発育したほとんどのコロニーは赤く発色します。

[判定上の注意事項]

- 1)シート状培地の面積は20cm²です。また、プレート底面には計測に便利な格子 (1 cm×1cm) を薄くつけてあります。菌数が多い場合は、代表的な格子内のコロニー数を算出して、その値に20を掛けて菌数を算出します。
- 2) 微生物の中にはTTCを還元しにくいものも存在します。このため、赤く発色しないコロニーが形成されることもあります。

── 使用上または取扱い上の注意事項 ─

1. 一般的な注意事項

- 1)この添付文書をよく読み、記載された操作法、注意に従って使用してください。
- 2) 使用期限を過ぎた製品は品質を保証できないので使用しないでください。
- 3)使用前に容器の破損、異物混入、変色、吸湿等の異常が認められた培地は使用しないでください。
- 4)残ったプレートは、アルミ袋に入れ、テープ止めをして防湿および遮光保存し、 早めに使用してください。特にTC (一般生菌数測定用) は光により培養後の コロニーの発色に影響を受けるので注意してください。

2. 危険防止上の注意事項

- 1) 試薬等が目や口に入った場合には、水で十分に洗い流し、医師に相談し、指示を受けてください。
- 2) 微生物の取り扱いは常に感染の危険があるので、取り扱いにあたっては熟練した人の指導のもとに、バイオハザード対策を実施したうえで使用してください。
- 3) 検体に接触した器材、培地等は感染の危険があるものとして取り扱いください。

3. 廃棄上の注意事項

使用済みの培地は高圧蒸気滅菌または十分に煮沸するなど殺菌処理をしたのちに 廃棄してください。

――― 貯法・使用期限 ―――

[貯法]

室温 (1~30℃) に保存してください。

* [使用期限]

製造後24ヵ月間。

外箱のラベルおよびプレートのアルミ袋に使用期限を表示してあります。

* * — 包装単位 — —

* * ------ 問い合わせ先 -----

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(SY3C1S)

** CompactDry TC

Simple and Easy Dry Medium for Total Viable Count

* *Background

It is important to detect and measure the total viable count in foodstuffs and the food environment to monitor the degree of cleanliness as well as sanitary safety. The pour plate method has been widely used to determine microbial counts. The pour plate method is time consuming and complicated, requiring operations such as preparation of hot agar maintained at $45 - 50^{\circ}\text{C}$, and uniform mixing and dilution. To save operator time and make it possible for anyone to perform the microbial count test without difficulty, the CompactDry™ was developed based on a new concept and technology applicable to the food industry. CompactDry™ requires a simple and easy manipulation to add a drop of specimen on the device.

Features and Benefits

- 1) Small and compact plate: Need only small physical spaces for storing, testing and incubating.
- Ready to use and portable plate: No need to prepare medium, which eliminates the waste of medium as well as the apparatus to prepare the medium. Good for emergency and field testing.
- Sample diffuses automatically and evenly into the plate: No need to mix and dilute after sampling.
- *4) Dried plate with 24 month shelf life at room temperature: Easy to store. Once a liquid sample is added, the dry coated medium transforms to gel and the plate is ready to incubate.
- Clear color development by redox indicator: Easy to read the results. Isolated colonies can be subcultured individually to other media.

 6) Good correlation with Pour Plate method: Maintain the continuity of data
- accumulated.

certified by the AOAC Research Institute Performance Tested Methods $^{\rm SM}$ Program (Certificate No. 010404) for enumeration of total viable counts in raw meat (raw ground beef, raw ground pork, raw pork, raw lamb, and raw veal). A matrix extension comparing the CompactDry $^{\text{TM}}$ TC to ISO 4833:2003 for cooked chicken, fresh pre-washed bagged shredded iceberg lettuce, frozen cod filets, instant non-fat dry milk, and pasteurized 2% milk was approved in 2015.

A matrix extension to raw chicken breast with enumeration at 24 h and 48 h

and a modification for raw ground beef for enumeration at 24 h compared to FSIS MLG 3.02 were approved in 2020.

* * Test Kit Components

CompactDry[™] TC Plates

Additional Reagents and Supplies Required, Not Provided

- 1) Butterfield's phosphate-buffered diluent (BPBD) Prepare according to AOAC **966.23**
- Maximum recovery diluent (MRD) Prepare according to ISO 4833:2003.
- 3) Filtered Stomacher bags.

Apparatus

- 1) Blender or StomacherTM or equivalent for homogenizing sample
- 2) Pipets 1 mL
- 3) Incubator $-35 \pm 1^{\circ}$ C (raw meat products) or $30 \pm 1^{\circ}$ C (all other matrices)

Operating Procedure

Preparation of specimen

- Prepare appropriate diluent: Butterfield's phosphate-buffered diluent (BPBD) for raw meat products or Maximum Recovery Diluent (MRD) for other claimed matrices. Autoclave for sterilization.
- Viable count in solid foodstuffs
 - For raw meat, weigh 50 g of sample and add 450 mL BPBD to the sample. Homogenize by blender for $2 \text{ min } \pm 15 \text{ s.}$ For cooked chicken, fresh lettuce, or frozen fish, weigh 10 g of sample and add 90 mL MRD. Homogenize by Stomacher for 1 min \pm 10s. For milk powder, weigh 10 g of sample and add to 90 mL MRD pre-warmed to 45 \pm 1°C. Slowly swirl and shake until sample is dissolved.
- Viable count in liquid foodstuffs
 - For pasteurized milk, use without dilution, dilute 1 mL in 9 mL MRD., or dilute further if viable count is >300 CFU/plate. Vortex to mix.
- Viable count in swab test sample (not included in AOAC PTM certification) Wiping solution, which is obtained from cotton swab, is used without dilution or diluted in MRD. It is recommended to use Swab Test ST-25PBS (Code 06698) available as an optional kit.

Direction for CompactDry™ TC

- Open aluminum bag, and take out a set of 4 plates.
- Detach necessary number of plate(s) from a set of four by bending up and down while pressing the lid. Use a set of four plates being connected when serial dilution measuring is intended.
- Remove cap from plate, pipette 1 mL of sample (to be diluted further if necessary) in the middle of the dry sheet, and replace cap. Specimen diffuses automatically and evenly over the entire sheet (total medium of 20 cm²) to transform it into a gel within seconds.
- Write the appropriate sample information in the memorandum section. Invert the capped plate and place in incubator at $35 \pm 1^{\circ}$ C for raw meat or $30 \pm 1^{\circ}$ C for all other matrices. Incubate 48 ± 3 h.
- 5) From the backside of the plate, count the number of colonies (colored and colorless) 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.
- Enumeration range of CompactDry™ TC is 1-300 CFU/plate. Specimen should be diluted in buffer to obtain a concentration level less than 300 CFU/plate.

Precaution for use

- 1) Do not use CompactDryTM TC for human and animal diagnosis.
- To avoid microbial contamination, do not touch the surface of the dry sheet medium during inoculation.
- During incubation, keep cap tight to avoid any possible dehydration.
- Use of filtered stomacher bags is recommended to eliminate risks of carryover of tiny pieces of foodstuffs onto the surface of the medium.
- If more than 10⁴ cfu/mL were inoculated onto a plate, no distinguishable colored colonies will form and the entire plate will become colored.
- 6) If the nature of the sample affects the reaction of the medium, inoculate the sample only after the factor has been eliminated by means such as dilution, pH adjustment or other. This may include samples with high viscosity, that are colored, that react with the redox indicator, or that have too high or too low pH.

Interpretation

- The medium consists of non-selective medium and the redox indicator 2,3,5-Triphenyl Tetrazolium Chloride (TTC). Colonies grown on CompactDry™ TC are almost all red colored.
- The full plate size is 20 cm². The backside contains carved grids of 1 cm x 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 x 1 cm), counted from several grids, and multiplying by 20. Alternatively, the total viable count can be obtain by averaging the number of colonies per small grid (0.5 cm x 0.5 cm), counted from several grids, and multiplying by 80.
- Since some microorganisms may not reduce TTC to develop red/pink color, colonies may develop on CompactDry™ TC that are not necessarily red. All colonies should be counted.

Warning and Direction for Use

General precautions

- 1) Read and follow precisely the warnings and directions for use described in the package insert and/or label.
- Do not use the product after its expiration date. Quality of the product is not warranted after its shelf life.

 Do not use product that contains any foreign materials, is discolored or
- dehydrated, or has a damaged container.
- Use plates as soon as possible after opening. Return any unused plates to the aluminum bag and seal with tape to avoid light and moisture. CompactDry $^{\text{TM}}$ TC (for total viable count) is sensitive to light, which affects the color development of colonies.
- 5) Cap tightly after inoculation to avoid dehydration of gelled medium.

Safety Precautions

- 1) If medium or reagent comes into contact with eyes or mouth, immediately wash with water and consult a physician.
- 2) Manipulations with microorganisms involve certain risks of laboratoryacquired infections. Manipulations should be carried out under the supervision of trained laboratory personnel with biohazard protection measures.
- Treat any laboratory equipment or medium that comes into contact with the specimen as infectious and sterilize appropriately.

 3. Precautions for disposal of waste

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

4. User Responsibility

- It is 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.
- 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

 $CompactDry^{\tiny{TM}} \ plates \ are \ manufactured \ at \ ISO \ 9001:2015 \ facility.$ 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. These are the exclusive remedies.

* Storage and Shelf life

Storage: Keep at room temperature $(1-30^{\circ}\text{C})$ Shelf life: Twenty-four (24) months after manufacturing. Expiration date is printed on outer box label and aluminum bag label.

* * Package

* * Further information

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