菌数測定用簡易培地 一般生菌数測定用(迅速タイプ)

** コンパクトドライ™ TCR

** ---- 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™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測定が できます。

コンパクトドライ $^{\text{TM}}$ TCRは一般生菌数迅速測定用の簡易培地であり、コンパクトドライ $^{\text{TM}}$ TCよりも迅速な 24 時間培養での測定ができます。

[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相関性があります。

—— 操作法——

[試料の調製、接種方法]

1. 固形食品材料の菌数測定

材料に希釈水を添加し、ストマッカーで均質化します。試料液 $1 \, \text{mL}$ (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 1 mL (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プレートを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 $20~{\rm cm}^2$) 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、乳製品以外の食品は 35 ± 1 ℃で、乳製品 (低温殺菌乳、生クリーム、脱脂粉乳) は 35 ± 1 ℃又は 32 ± 1 ℃で、 48 ± 3 時間培養します。

迅速測定を行う場合には、乳製品以外の食品は $35 \pm 1 \, \mathbb{C}$ で、乳製品(低温殺菌乳、生 クリーム、脱脂粉乳)は $35 \pm 1 \, \mathbb{C}$ 又は $32 \pm 1 \, \mathbb{C}$ で、 24 ± 2 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。
- 6) 試料は1プレートあたり300 cfu以下になるように希釈水などで希釈してから接種しま

----- 操作上の注意事項 ----

- 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) 食品自体が培地の反応に影響を与えるものは、希釈水などで希釈する等、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、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が含まれており、発育したほとんどのコロニーが赤く発色 します。

[判定上の注意事項]

- ** 1) 微生物の中には酸化還元指示薬を還元しにくいものも存在し、コロニーが赤色〜ピンク 色に発色する場合があります。コンパクトドライ™ TCR上に発育したコロニーはす べて計数してください。
 - 2) 1 プレートあたり 10^4 cfu 以上の菌が接種されると、計数可能な大きさのコロニーが形成されず、シート全体が着色したようになる場合があります。

3) シート状培地の面積は20 cm²です。また、プレート底面には計測に便利な格子(1 cm × 1 cm)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。

---- 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、注意事項に従って使用してください。
- 2) ヒト及び動物の診断に使用しないでください。
- 3) 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。
- 4) 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。
- ** 5) 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。特にコンパクトドライ™ TCRは光により培養後のコロニー発色 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ってください。

3. 廃棄上の注意事項

使用済みの培地は高圧蒸気滅菌したのちに廃棄してください。

_____ **贮法·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 18ヶ月間。

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。

** **一 包装単位** ー コンパクトドライ™ TCR 40 枚 ・・・・・・・・・・・・・・・・・・・・・・・・・ Code 06539 コンパクトドライ™ TCR 240 枚 ・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・ Code 06540

** -----問い合わせ先----

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** CompactDry TCR

Simple and Easy Dry Medium for aerobic counts (Rapid type)

* * Background

It is important to detect and measure the aerobic counts 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°C, and uniform mixing and dilution. To save operator time and make it possible for anyone to perform the microbial count test without difficulty, Shimadzu Diagnostics Corporation developed the CompactDryTM based on a new concept and technology applicable to the food industry. CompactDryTM requires a simple and easy manipulation to add a drop of specimen on the device.

CompactDryTM TCR is specially formatted to allow most microorganisms to grow more rapidly than the standard CompactDryTM TC.

Features and Benefits

- Small and compact plate: Need only small physical spaces for storing, testing and 1)
- 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.
- Dried plate with 18 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.
- Good correlation with Pour Plate method: Maintain the continuity of data

*Intended Use

This product is intended for use by microbiologists for the enumeration of aerobic bacteria in food and related samples.

*Certification by AOAC

The CompactDry™ TCR has been compared to FSIS MLG Chapter 3.02 and certified by the AOAC Research Institute Performance Tested MethodsSM Program (Certificate No. 082201) for enumeration of aerobic mesophilic counts in raw ground beef, raw ground pork, raw pork and raw chicken breast, and compared to FDA BAM Chapter 3 and certified in raw shrimp, raw cod, bagged pre-washed shredded iceberg lettuce and bagged pre-washed mixed lettuce and vegetables. And it also has been compared to APHA SMEDP Chapter 6 and certified in pasteurized whole milk, nonfat dry milk, and pasteurized heavy cream.

* * Test Kit Components

1) CompactDryTM TCR Plates

Additional Reagents and Supplies Required, Not Provided

- Butterfield's phosphate-buffered diluent (BPBD) Prepare according to FDA BAM R11
- 2) Filtered Stomacher bags

Apparatus

- Blender or StomacherTM or equivalent for homogenizing sample
- 2) Pipets - 1 mL
- 3) $Incubator - 35 \pm 1^{\circ}C \; (all \; claimed \; matrices \; except \; dairy \; products)$ $35\pm1^{\circ}\text{C}$ or $32\pm1^{\circ}\text{C}$ (pasteurized whole milk, nonfat dry milk and heavy cream)

Operating Procedure

Preparation of specimen

- Prepare appropriate diluent: Butterfield's phosphate-buffered diluent (BPBD). Autoclave for sterilization.
- Viable count in solid foodstuffs (all claimed matrices except dairy products) Weigh 50 g of sample and add 450 mL BPBD to the sample. Homogenize by blender for 2 min.
- Viable count in solid foodstuffs (nonfat dry milk)
 Weigh 11 g of sample and add 99 mL BPBD to the sample. Homogenize by blender for 2 min.
- Viable count in liquid foodstuffs (pasteurized whole milk and heavy cream) Weigh 11 mL of sample and add 99 mL BPBD to the sample. Homogenize by blender for 2 min.
- Viable count in swab test sample (not included in AOAC PTM certification) Use wiping solution (without dilution or diluted if necessary in diluent) obtained from the cotton swab. It is recommended to use Swab Test ST-25PBS (Code 06698) available as an optional kit.

* * Direction for CompactDry™ TCR

- Open aluminum pouch, 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
- Remove the lid from plate, pipette 1 mL of sample (to be diluted further if necessary) in the middle of the dry sheet, and replace the lid. 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 lidded plate lidand place in incubator at 35 ± 1 °C for all claimed matrices except dairy products, or 35 ± 1 °C or 32 ± 1 °C for pasteurized whole milk, nonfat dry milk and heavy cream for 48 ± 3 h. In case of rapid measurement, incubate $35 \pm$ 1°C for all claimed matrices except dairy products, or 35 ± 1 °C or 32 ± 1 °C for pasteurized whole milk, nonfat dry milk and heavy cream for 24 ± 2 h.
- 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™ TCR is 1–300 cfu/plate. Specimen should be diluted in buffer to obtain a concentration level less than 300 cfu/plate.

Precaution for use

- Do not use CompactDry™ TCR for human and animal diagnosis.
 - To avoid microbial contamination, do not touch the surface of the dry sheet 2) medium during inoculation.
- During incubation, keep lid 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 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.

The medium consists of non-selective medium and the redox indicator. Colonies grown on CompactDry $^{\text{TM}}$ TCR are almost all red colored.

Precaution for interpretation

- Since some microorganisms may not reduce the redox indicator to develop red/pink color, colonies may develop on CompactDry $^{\text{TM}}$ TCR that are not necessarily red. All colonies should be counted.
 - If more than 10⁴ cfu/mL were inoculated onto a plate, no distinguishable colored colonies will form and the entire plate will become 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 aerobic counts 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 aerobic counts 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.

Warning and Direction for Use

1. 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 pouch and seal with tape to avoid light and moisture. CompactDry™ TCR (for aerobic counts) is sensitive to light, which affects the color development of colonies.
- *5) Lid 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.
- Manipulations with microorganisms involve certain risks of laboratory acquired 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

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.

 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 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: Eighteen (18) months after manufacturing.

Expiration date is printed on outer box label and aluminum pouch label.

* * Package

CompactDryTM TCR CompactDryTM TCR

* *Further information

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