

**REF - KM0003**

## Instructions for Use

### Sabouraud Dextrose Agar

### Dehydrated Culture Media

#### 1. Intended Use

For *in vitro* diagnostic use. KM0003 Sabouraud Dextrose Agar powder is a general-purpose, non-selective medium which is used for the isolation of yeasts and moulds from clinical, food, pharmaceutical and cosmetic samples.

#### 2. Composition\*

| <u>Ingredient</u> | <u>g/L</u> |
|-------------------|------------|
| Tryptone          | 5.0        |
| Meat peptone      | 5.0        |
| Dextrose          | 40.0       |
| Agar              | 15.0       |

\*Adjusted/supplemented as needed to meet performance requirements

#### 3. Summary and Explanation

KM0003 Sabouraud Dextrose Agar may be used for the isolation of pathogenic fungi from clinical, food, cosmetics, and pharmaceutical samples. It may also be used as a settle-plate to determine fungal contamination in clean-room atmospheres.

Sabouraud Dextrose Agar is a modification of a medium originally described by Sabouraud <sup>(1)</sup>. The fungi maintain their typical cultural appearance and thus may be readily identified according to the standard macroscopic characters described by Sabouraud. The formulation conforms to European, United States and Japanese Pharmacopeia requirements <sup>(2 3 4)</sup>. This medium complies with ISO 11133:2014, where it is described as the main reference medium to carry out quantitative testing on culture media intended for fungi <sup>(5)</sup>.

Sabouraud Dextrose Agar is recommended by the UK Standards for Microbiology Investigations <sup>(6)</sup> for various purposes, including as a standard, supplementary or optional medium.

#### 4. Principle

The medium contains tryptone and meat peptone to supply the nitrogen and vitamins needed for growth. The high concentration of glucose (dextrose) is included as an energy and carbon source and, in tandem with the acidic pH (5.6), facilitates growth of fungi, especially dermatophytes, while providing inhibitory activity against bacteria <sup>(7)</sup>. The yeasts develop creamy to white colonies. The fungi will grow as filamentous colonies of different colours.

#### 5. Preparation Instructions

Suspend 65.0g of dehydrated culture medium in 1 litre of deionised/purified water and allow to soak whilst mixing for 10 minutes.

Autoclave to sterilise at 121°C for 15 minutes before cooling in a water bath to 45-50°C.

Aseptically dispense the specified volume into appropriate sterile containers and allow to cool.

NB: Avoid overheating this medium as the acidic pH may result in a softer final medium.

#### 6. Physical Characteristics

|                       | Dehydrated Medium | Prepared Medium |
|-----------------------|-------------------|-----------------|
| Appearance and Colour | Straw fine powder | Straw firm gel  |
| pH                    | N/A               | 5.6 ± 0.2       |

#### 7. Materials Provided

KM0003 can be provided in the formats detailed below. Each tub is labelled with product name, product code, lot number, expiry date, instructions, and appropriate warnings.

| <b>Product Code</b> | <b>Product Format</b>                 |
|---------------------|---------------------------------------|
| KM0003-500G-500     | 1 x 500g Dehydrated Culture Media Tub |
| KM0003-5KG-5000     | 1 x 5kg Dehydrated Culture Media Tub  |
| KM0003-10KG-10000   | 1 x 10kg Dehydrated Culture Media Tub |

#### 8. Materials Needed but not Provided

Standard microbiological laboratory materials *e.g.*, autoclave, sterile loops or swabs, collection containers, incubators, and quality control organisms.

## 9. Specimens

KM0003 Sabouraud Dextrose Agar can be used with the following specimens:

- Clinical: Including but not limited to skin swabs taken from infected locations including hair and nail, nasal aspirate and washout, mouth swabs, saliva, oral rinse and fluids from normally sterile sites <sup>(5)</sup>
- Food and Environmental: products for human consumption, animal feed and environmental samples
- Pharmaceuticals and Cosmetics: Finished product, raw materials, environmental testing of surfaces and equipment.

Sampling and transport equipment must be used in accordance with the end user's suppliers' recommendations. Refer to appropriate standard method or local guidance on sample collection & subsequent processing.

## 10. Test Procedures and Interpretation of results

Allow media manufactured to come to room temperature.

Based on sample type and information provided, check to see if the specimen needs to be pre-enriched prior to inoculation to the prepared medium.

### Food and Environmental Specimens:

For solid samples, prepare a homogenised suspension using a ratio of 1:10 of sample to Maximum Recovery Diluent (E&O BM0760). With homogenised and liquid specimens, media should be inoculated with 1ml of the specimen.

### Clinical Specimens:

Inoculate specimen, or pre-enriched sample, directly onto the medium and streak across the agar surface using a sterile loop or automated plate streaker.

### Pharmaceutical and Cosmetic Specimens:

For solid or viscous samples, prepare a homogenised suspension using a ratio of 1:10 of sample to Letheen Broth Modified (E&O BM4284). With homogenised and liquid specimens, media should be inoculated with 1ml of the specimen.

Incubate plates at 25-30°C and examine the plates every 2 to 3 days for colonies for up to 10 days (typical colony appearance outlined in Quality Control table below). Perform further biochemical, serological, or mass spectroscopy testing to confirm identity of presumptive positive isolates. Refer to relevant local guidelines.

## 11. Quality Control

| Organism                           | Incubation           | Result (Specificity)                                                           |
|------------------------------------|----------------------|--------------------------------------------------------------------------------|
| <i>T. rubrum</i> (NCPF 419)        | 25-30°C for 2-7 days | Growth: White fluffy colonies with dark red/brown underside (ISO)              |
| <i>A. brasiliensis</i> (NCPF 2275) | 25-30°C for 2-7 days | Growth: White colonies with black pigmentation, pale yellow reverse (USP, ISO) |
| <i>C. albicans</i> (NCPF 3179)     | 25-30°C for 2-7 days | Growth: White colonies (USP, ISO)                                              |
| <i>A. fumigatus</i> (DSMZ 819)     | 25-30°C for 2-7 days | Growth: White colonies with blue/green pigmentation, pale yellow reverse (ISO) |
| <i>S. cerevisiae</i> (NCPF 3178)   | 25-30°C for 2-7 days | Growth: White colonies (ISO)                                                   |

It is the responsibility of the user to perform Quality Control testing taking into consideration the intended use of the medium and in agreement with any local relevant guidelines (e.g., frequency, strains used, atmosphere, incubation temperature).

## 12. Performance

To fully verify KM0003 Sabouraud Dextrose Agar performance, dehydrated culture media samples were used to prepare Sabouraud Dextrose Agar poured plates and tested to assess colony morphology and recovery level (where an acceptable range is ≥70% and ≤120%) compared to a non-selective reference medium. Prepared samples were inoculated with 30-150cfu and incubated at 25-30°C for 2-7 days. All samples of prepared media showed expected recovery and morphology of the required test organisms: *Trichophyton rubrum* (NCPF 419), *Aspergillus brasiliensis* (NCPF 2275), *Candida albicans* (NCPF 3179), *Aspergillus fumigatus* (DSMZ 819) and *Saccharomyces cerevisiae* (NCPF 3178). Therefore, it can be concluded that KM0003 Sabouraud Dextrose Agar, meets performance criteria when used according to the instructions outlined above. Trend analysis data available upon request.

## 13. Limitations of the Media

- This medium does not promote conidiation of filamentous fungi.
- Additional biochemical, serological, or molecular tests should be performed on sub-culture isolates to confirm identity.
- Due to natural variation, some strains may grow poorly on this medium.
- Agents added to this medium to inhibit bacteria may also inhibit certain pathogenic fungi.

## 14. Precautions and Warnings

This product is considered non-hazardous under CLP regulations. Wear such PPE as recommended by laboratory COSHH assessment. During and after use, always handle all materials in a manner conforming to Good Laboratory Practices and consider that material under test should be regarded as a potential biohazard if mishandled.

Refer to KM0003 Material Safety Data Sheet.

## 15. Storage conditions and Shelf life

Store product in the original container with the lid tightly closed at between 10 and 30°C in low humidity conditions away from direct sunlight. Kept under these conditions, the product may be used up to the date of expiry shown on the product label.

Do not use if the product is not free-flowing or displays any sign of colour change, formation of large lumps or hardening of the powder. Additionally, do not use medium if it has been stored inappropriately, the packaging has been damaged or has passed the expiry date.

Dehydrated culture media does not need to be used all at once; replace the cap and ensure that the container is tightly closed and stored according to labelled instructions.

Dispose of in accordance with local and national authority requirements.

## 16. References

1. Sabouraud, R. (1892) Contribution a l'étude de la trichophytie humaine. Etude clinique, microscopique et bacteriologique sur la pluralité des trichophytons de l'homme. Annual Dermatology Syphilis, 3, 1061-1087.
2. Council of Europe (2019) European Pharmacopoeia. 10th ed., Strasbourg: Council of Europe.
3. United States Pharmacopeial Convention (2019) The United States Pharmacopeia USP42, The National Formulary NF37. Rockville, MD: United States Pharmacopeial Convention.
4. The Ministry of Health, Labour and Welfare (2021) The Japanese Pharmacopoeia. 18th ed. Tokyo: Yakuji Nippo Limited.
5. International Organization for Standardization (2014) 11133:2014 Microbiology of food, animal feed and water - Preparation, production, storage and performance testing of culture media. Geneva, ISO.
6. Public Health England. UK Standards for Microbiology Investigations. Bacteriology. London: Standards Unit, Microbiology Services.
7. Ali, S., Fradi, A. and Al-araji, A. (2017) Effect of some physical factors on growth of five fungal species. Eur. J. Acad. Res., 2, 1069-1078.

## Version History\*

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|-----|-------------------------------------------------------------------|
| 001 | 02/03/2023 - New document created                                 |
| 002 | 07/03/2025 - Updated to new format in line with new documentation |

\*Note: minor typographical, grammatical, and formatting changes are not included in the revision history.



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IFU/KM0003 REV. 002

TABLE OF APPLICABLE SYMBOLS

|                                                                                                                       |                                                                                                                                            |                                                                                                                                                   |                                                                                                                                |                                                                                                                       |
|-----------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
|  <b>REF</b><br>Catalogue number    |  <b>LOT</b><br>Batch code                               |  <b>IVD</b><br><i>In vitro</i><br>Diagnostic<br>Medical Device |  <b>Manufacturer</b>                        |  <b>Use by</b>                   |
|  <b>Temperature<br/>limitation</b> |  <b>Contents<br/>sufficient for<br/>&lt;n&gt; tests</b> |  <b>Consult<br/>Instructions for<br/>Use</b>                   |  <b>Keep away<br/>from direct<br/>light</b> |  <b>Store in a dry<br/>place</b> |