

INSTRUCTIONS FOR USE

DERMATOPHYTE SELECTIVE MEDIUM (DTM)

Ready-to-use plates

Trichophyton mentagrophytes on DTM

1 - INTENDED USE

In vitro diagnostic, differential medium for the detection of dermatophyte fungi from cutaneous specimens.

2 - COMPOSITION TYPICAL FORMULA*

Soy peptone	11.0 g
Glucose	10.0 g
Phenol red	0.2 g
Cycloheximide	0.5 g
Gentamicin sulphate	0.1 g
Chlortetracycline HCl	0.1 g
Agar	15.0 g
Purified water	1000 mL

*the formula may be adjusted and/or supplemented to meet the required performances criteria.

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

The dermatophyte fungi are classified in three genera: *Epidermophyton* spp., *Microsporum* spp. and *Trichophyton* spp. The most common dermatophyte infections are *tinea pedis* (athlete's foot), *tinea unguium* (nail infection) in adults and *tinea capitis* (scalp ringworm) in children.¹

Dermatophyte Test Medium or DTM has been formulated by Taplin, Zaias and Rebell² in 1969; ready-to-use plates are prepared according to the formula of Taplin *et al.* and are intended for selective isolation and differentiation of dermatophyte fungi responsible for lesions of the skin, nails, hair.¹

Soy peptone provide the nutrients for microbial growth. Glucose is a source of carbon and energy for enhancing dermatophytes growth. Phenol red is a pH indicator, used to detect acid/alkaline production and to differentiate dermatophytes that cultivate with a change to red of the medium because of the production of basic metabolites. The antimicrobials included in the medium partially suppress the growth of bacteria and fungi: cycloheximide inhibits most saprophytic moulds, gentamicin inhibits most Gram-negative and some Gram-positive bacteria, chlortetracycline has a bacteriostatic activity against a wide range of microorganisms including Gram-positive and Gram-negative.

The medium allows the diagnosis of dermatophytes after at least 48 hours of incubation.

Allen³ reported an accuracy of 97% in the identification of dermatophytes with the DTM medium; several authors⁴⁻⁷ reported that DTM is an effective and convenient medium for confirming dermatophyte infections in Laboratory and in-office.

4 - PHYSICAL CHARACTERISTICS

Appearance	orange, limpid
Final pH at 20-25°C	5.5 ± 0.2

5 - MATERIALS PROVIDED – PACKAGING

Product	Type	REF	Pack
Dermatophyte Selective Medium (DTM)	Ready-to-use plates	541369	2 x 10 plates ø 90 mm primary packaging: 2 cellophane sachets secondary packaging: cardboard box

6 - MATERIALS REQUIRED BUT NOT PROVIDED

Incubator and laboratory equipment as required, sterile loops and swabs, ancillary culture media and reagents for the identification of the colonies.

7 - SPECIMENS

DTM is intended for the examination of cutaneous specimens such as nails, hair, skin.¹ Collect specimens before antimicrobial therapy where possible. Good laboratory practices for collection, transport and storage of the specimens should be applied.¹

8 - TEST PROCEDURE

Allow plates to come to room temperature.

Press cutaneous specimens by gently pressing lightly the samples onto the agar surface.

Incubate aerobically, at 23-27°C for 4-7 days.

Negative cultures can be reported after 7 days, but plates should be re-incubated for a further week and examined before discarding at two weeks.¹

9 - READING AND INTERPRETATION

After incubation observe the microbial growth and record the specific morphological and chromatic characteristics of the colonies.





Dermatophytes produce alkaline metabolites which elevate the pH of the medium inducing a colour change of phenol red from orange to red. Examine the medium for evidence of white or light pinkish aerial growth and of a pink to red colour in the medium. For fast-growing dermatophytes, the red colour appears after 48 hours of incubation; for slow-growing dermatophytes, 3 to 7 days of incubation are required. When there are small colonies, the red colour remains limited to the area around the colony; when the growth is confluent and conspicuous, the indicator changes over the entire plate.

10 - USER QUALITY CONTROL

All manufactured lots of the product are released for sale after the Quality Control has been performed to check the compliance with the specifications. However, the end user can perform its own Quality Control in accordance with the local applicable regulations, in compliance with accreditation requirements and the experience of the Laboratory. Here below are listed some test strains useful for the quality control.

CONTROL STRAINS	INCUBATION T° / T / ATM	EXPECTED RESULTS
<i>T. mentagrophytes</i> ATCC 9533	23-27°C / 94-96h / A	growth, white iphae, the medium turns red-violet
<i>C. albicans</i> ATCC 10231	23-27°C / 94-96h / A	good partially inhibited, white colonies
<i>A. brasiliensis</i> ATCC 16404	23-27°C / 94-96h / A	inhibited
<i>E. coli</i> ATCC 25922	23-27°C / 94-96h / A	inhibited

A: aerobic incubation; ATCC is a trademark of American Type Culture Collection

11 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of ready-to use plates of Dermatophyte Selective Medium (DTM) and of the raw material used for the production of prepared plates, dehydrated Dermatophyte Selective Medium-DTM- (Taplin) supplemented with Dermatophyte Antimicrobial Supplement, are tested for productivity and selectivity by comparing the results with previously approved Reference Batches.

Productivity characteristics are tested by semi-quantitative ecometric technique with the following target strains: *Microsporium canis* ATCC 36229, *Trichophyton rubrum* ATCC 28188, *Trichophyton mentagrophytes* ATCC 9533 After incubation at 23-27°C for 96 hours, typical colonies develop white aerial hyphae with an alkalisation of the medium that turns to red.

Selectivity is evaluated with modified Miles-Misra surface drop method by inoculating the plates with suitable decimal dilutions in saline of a 0.5 McFarland suspension of the non-target strains *C. albicans* ATCC 10232, *A. brasiliensis* ATCC 16404, *S. cerevisiae* ATCC 9763, *E. coli* ATCC 25922, *S. aureus* ATCC 25923. *C. albicans* is partially inhibited, the growth of other non-target strains is totally inhibited.

12 - LIMITATIONS OF THE METHOD

- Saprophytes may redden the medium if specimen material is heavy contaminated but they can be recognized by their dark green or black hyphae; dermatophytes exhibit white aerial hyphae.⁸
- Disregard any colour after 10 days of incubation; it may be due to growth of contaminants.⁸
- A medium containing cycloheximide should not be used when infection with a non-dermatophyte mould is likely or suspected.¹
- The use of DTM should be combined with morphological study, since dermatophytoides, usually non pathogenic, such as the *Trichophyton terrestre* complex as well as various *Chrysosporium* species and other nondermatophytic fungi can grow and turn the medium red.⁹
- DTM may uncommonly give false-negative results with some *Microsporium* isolates.⁹
- Even if the microbial colonies on the medium are differentiated on the basis of their morphological and chromatic characteristics, it is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on isolates, from pure culture, for complete identification. If relevant, perform antimicrobial susceptibility testing.
- This culture medium is intended as an aid in the diagnosis of infectious diseases; the interpretation of the results must be made considering the patient's clinical history, the origin of the sample and the results of other diagnostic tests.

13 - PRECAUTIONS AND WARNINGS

- This product is a qualitative *in vitro* diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- This product is not classified as dangerous according to current European legislation.
- This culture medium contains raw materials of animal origin. The *ante* and *post mortem* controls of the animals and those during the production and distribution cycle of the raw materials, cannot completely guarantee that the product doesn't contain any transmissible pathogen. Therefore, it is recommended that the ready-to use plates be treated as potentially infectious, and handled observing the usual specific precautions: do not ingest, inhale, or allow to come into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website www.biolifeitaliana.it, describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as culture medium or microbial agents.
- Each plate of this culture medium is for single use only.
- Ready-to-use plates are not to be considered a "sterile product" as they are not subject to terminal sterilization, but a product with controlled biocontamination, within the limits of defined specifications reported on the Quality Control Certificate.
- Sterilize all biohazard waste before disposal. Dispose the unused medium and the sterilized plates inoculated with samples or microbial strains in accordance with current local legislation.
- The Certificates of Analysis and the Safety Data Sheet of the product are available on the website www.biolifeitaliana.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.



**14 - STORAGE CONDITIONS AND SHELF LIFE**

Upon receipt, store plates in their original pack at 2-8°C away from direct light. If properly stored, the plates may be used up to the expiration date. Do not use the plates beyond this date. Plates from opened plastic sachet can be used for 7 days when stored in a clean area at 2-8°C. Do not use the plates if the plastic sachet is damaged or if the dish is broken. Do not use the plates with signs of deterioration (e.g. microbial contamination, dehydration, shrinking or cracking of the medium, atypical colour, excess of moisture).

15 - REFERENCES

- Public Health England. Investigation of dermatological specimens for superficial mycoses. SMI B 39, Issue no: 3.1, 2016.
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TABLE OF APPLICABLE SYMBOLS

REF or REF Catalogue number	LOT Batch code	IVD <i>In vitro</i> Diagnostic Medical Device	 Manufacturer	 Use by
 Temperature limitation	 Contents sufficient for <n> tests	 Consult Instructions for Use	 For single use only	 Fragile, handle with care

REVISION HISTORY

Version	Description of changes	Date
Instructions for Use (IFU) - Revision 0	First emission	2020/09
Revision 1	Removal of obsolete classification	2023/03

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

