IFU

HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

SABHI AGAR

Cat. no. W75	SabHI Agar, 15x100mm Plate, 26ml	10 plates/bag
Cat. no. X75	SabHI Agar, 50ml HardyFlask™, 12ml	20 flasks/box
Cat. no. X73	SabHI Agar with Blood, Chloramphenicol and Cycloheximide, 50ml HardyFlask™, 12ml	20 flasks/box

INTENDED USE

Hardy Diagnostics SabHI Agar is recommended for use in the cultivation of fungi. SabHI Agar with Blood, Chloramphenicol, and Cycloheximide is recommended for the selective isolation of pathogenic fungi.

SUMMARY

Sabouraud designed Sabouraud Dextrose Agar for the cultivation of dermatophytes.[9] It is a general purpose medium that is used in qualitative procedures for the cultivation of dermatophytes and other pathogenic and non-pathogenic fungi from clinical and non-clinical specimens. Brain Heart Infusion Agar is used for the primary isolation and cultivation of fungi from clinical specimens.[2] Gorman, in 1967, combined the two mediums to produce SabHI Agar. The combined formulation yields greater recovery of pathogenic fungi than either medium individually.[8]

The incorporation of chloramphenicol and cycloheximide provides selectivity to the medium. Chloramphenicol inhibits a range of gram-positive and gram-negative bacteria; cycloheximide inhibits saprophytic molds but may also inhibit growth of some significant pathogens (e.g., *Cryptococcus neoformans*, some *Candida* species, some *Aspergillus* spp. and mucormycetes (formally zygomycetes)). Blood provides essential growth factors for the more fastidious fungal organisms. Gorman showed that the addition of blood increased the recovery of *H. capsulatum*.[8] Blood also aids in the conversion of *H. capsulatum* and *B. dermatitidis* to the yeast phase.

FORMULA

Ingredients per liter of deionized water:*

Dextrose	21.0gm
Brain Heart Infusion	10.0gm
Meat Peptone	7.25gm
Sodium Chloride	2.5gm
Casein Peptone	2.25gm
Disodium Phosphate	1.25gm
Agar	15.0gm

Additionally, SabHI Agar with Blood, Chloramphenicol and Cycloheximide contains:

Cycloheximide	500.0mg
Chloramphenicol	50.0mg
Sheep Blood	50.0ml

Final pH 7.0 +/- 0.3 at 25ºC.

* Adjusted and/or supplemented as required to meet performance criteria.

STORAGE AND SHELF LIFE

Storage: Upon receipt store Cat. nos. W75 and X73 at 2-8ºC away from direct light. Store Cat. no. X75 at 2-30ºC away from direct light. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), hemolysis, contamination, or if the expiration date has passed.

The expiration date on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below.

Refer to the document "Storage" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual Universal Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "Guidelines for Isolation Precautions" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

PROCEDURE

Specimen Collection: Infectious material should be submitted directly to the laboratory without delay and protected from excessive heat and cold. If there is to be a delay in processing, the specimen should be inoculated onto an appropriate transport media and refrigerated until inoculation. Consult listed references for information regarding the processing and inoculation of specimens.[2-6]

Method of Use: Inoculate a non-selective and selective medium in parallel to ensure recovery of pathogenic fungi from potentially contaminated specimens. Incubate aerobically at 25-30ºC with increased humidity for 30 days or longer. Inoculate two sets of media for isolation of fungi that cause systemic mycoses; incubate one set at 25-30ºC and the other set at 35 +/- 2ºC . Examine cultures weekly for a period of four weeks before being reported negative.

INTERPRETATION OF RESULTS

Media should be examined for characteristic colonial growth and morphology. Consult listed references for the interpretation of fungal growth on this medium.[2-6]

LIMITATIONS

For proper identification of fungi, microscopic examination and evaluation of morphological structures is required.

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

For selective media, specific strains of fungi for which the medium is designed to isolate often may be inhibited. Fungi for which the medium is designed to inhibit may grow.

A non-selective and selective medium should be inoculated for isolation of fungi from potentially contaminated specimens.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, swabs, applicator sticks, other culture media, incinerators, incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificate of Analysis (CofA) and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media*. The following microorganisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
SabHI Agar:					
Trichophyton mentagrophytes ATCC® 9533**	G	7 days	15-30°C	Aerobic	Growth
Candida albicans ATCC® 60193**	A	24-48hr	35°C	Aerobic	Growth
SabHI Agar with Blood, Chloramphenicol and Cycloheximide:					
Candida albicans ATCC® 10231**	A	48hr	35°C	Aerobic	Growth
Trichophyton mentagrophytes ATCC® 9533**	G	7 days	15-30°C	Aerobic	Growth
Aspergillus brasiliensis ATCC® 16404	G	7 days	15-30°C	Aerobic	Partial to complete inhibition
Escherichia coli ATCC® 25922**	B	24hr	35°C	Aerobic	Partial to complete inhibition

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

** Recommended QC strains for User Quality Control according to the CLSI document M22 when applicable.

USER QUALITY CONTROL

End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificate of analysis (CofA) available from Hardy Diagnostics Certificate of Analysis website. Also refer to the document "Finished Product Quality Control Procedures," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

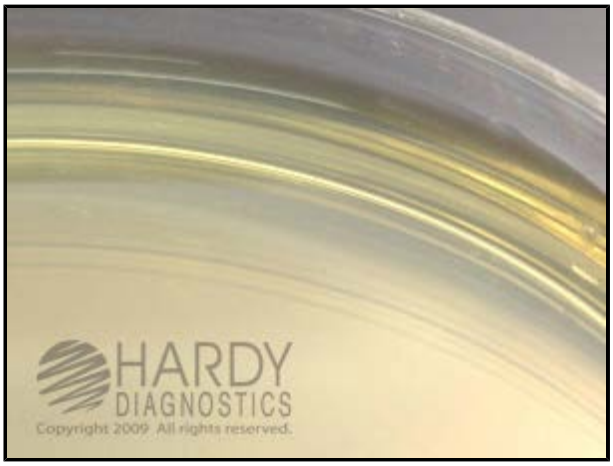
PHYSICAL APPEARANCE

SabHI Agar with and without antimicrobics, should appear clear, and amber in color.

SabHI Agar with Blood, Chloramphenicol and Cycloheximide should appear opaque, and cherry red in color.

Trichophyton mentagrophytes (ATCC® 9533) growing on SabHI Agar (Cat. no. W75). Incubated aerobically for 72 hours at 30ºC .

Candida albicans ATCC® 60193) colonies growing on SabHI Agar (Cat. no. W75). Incubated aerobically for 24 hours at 35ºC .



Uninoculated plate of SabHI Agar (Cat. no. W75).

REFERENCES

1. Anderson, N.L., et al. *Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory*, Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.

2. Jorgensen., et al. *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, D.C.

3. Tille, P., et al. *Bailey and Scott's Diagnostic Microbiology*, C.V. Mosby Company, St. Louis, MO.

4. *Cumitech 11; Practical Methods for Culture and Identification of Fungi in the Clinical Microbiology Laboratory* , American Society for Microbiology, Washington, D.C., 1980.

5. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.

6. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology*, 6th ed. J.B. Lippincott Company, Philadelphia, PA.

7. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

8. Gorman, J.W. 1967. *Am. J. Med. Technol.*; 33:151.

9. Sabouraud. 1892. *Ann. Dermatol. Syphil.*; 3:1061.

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

HDQA 2207F [D]