IFU

Instructions for Use

MALT EXTRACT AGAR

Cat. no. H57	Malt Extract Agar, 15x150mm Plate, 68ml	10 plates/bag
Cat. no. P93	Malt Extract Agar with Lecithin and Tween® 80, Contact Plate, 15ml	10 plates/bag
Cat. no. W28	Malt Extract Agar, 15x100mm Plate, 26ml	10 plates/bag
Cat. no. L128	Malt Extract Agar with 0.01% Chloramphenicol, 16x100mm Tube, 5.5ml slant	20 tubes/box
Cat. no. P80	Malt Extract Agar with Chloramphenicol, Contact Plate, 15ml	10 plates/bag
Cat. no. W80	Malt Extract Agar with Chloramphenicol, 15x100mm Plate, 26ml	10 plates/bag

INTENDED USE

Hardy Diagnostics Malt Extract Agar is recommended for the cultivation, isolation, and maintenance of yeasts and molds.

Cat. no. P80 and P93 are not intended to be used for the diagnosis of human disease.

SUMMARY

Fungal testing is conducted to identify the fungal impact on manufacturing processes, avoid structural damage that can accompany mold growth, as well as recognize fungal isolates that may compromise human health. In addition to being the etiologic agents for disease, fungi have the potential to produce allergens, irritants and, in some cases, potentially toxic substances (mycotoxins), which can induce an allergic response, cause asthma attacks, and irritate the eyes, skin, throat, and lungs of susceptible individuals.[8] Malt Extract Agar is used as a general purpose growth media to isolate and cultivate yeasts and molds from clinical samples, as well as a wide range of environmental sources.

Malt Extract Agar, based on the formula recommended by Thom and Church, is designed to contain the proper formulation of carbon, protein and nutrient sources essential for yeast and mold growth.[7] Dextrose is added to the medium to provide a carbon and energy source for fungi. Additionally, Malt Extract Agar contains digests of animal tissues (peptones) which provide a nutritious source of amino acids and nitrogenous compounds for the growth of mold and yeasts. The pH is adjusted to approximately 5.5 in order to enhance the growth of fungi and to slightly inhibit bacterial growth commonly found as environmental contaminants.[6] Chloramphenicol is added to increase the inhibitory properties of Malt Extract Agar with Chloramphenicol (Cat. no. P80 and W80) to inhibit bacterial overgrowth while permitting successful selective isolation of fungi and yeasts. Malt Extract Agar with Lecithin and Tween® 80 can be used to test the efficacy of disinfection procedures.

FORMULA

Ingredients per liter of water:*

Malt Extract Agar:

Malt Extract	20.0gm
Dextrose	20.0gm
Peptone	6.0gm
Agar	15.0gm

Final pH 5.5 +/- 0.3 at 25ºC.

In addition to the above ingredients, Malt Extract Agar with Chloramphenicol contains 0.1gm of chloramphenicol per liter and Malt Extract Agar with Lecithin and Tween contains 5.0gm Tween and 0.7gm Lecithin per liter.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store plated media at 2-8ºC., away from direct light. Upon receipt store tubed/bottles media at 2-30ºC. away from direct light. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

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

For Cat. nos. H57, L128, W28 and W80.

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.

For Cat. nos. P93 and P80.

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 blood precautions. Do not ingest, inhale, or allow to come into contact with skin.

This product is for laboratory 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: It is important to take proper cautions when cleaning mold contaminated areas, in order to limit exposure to mold and mold spores. It is recommended that while cleaning an area potentially contaminated with fungi that one wears a N-95 respirator, gloves, and goggles. For additional information consult the listed reference.[8]

1. Allow media to warm to room temperature, and the agar surface to dry before inoculating.

2. Using a needle, loop, or swab remove a small amount of mature growth from the area to be cultured. Inoculate and streak the sample as soon as possible after collection.

3. If the specimen to be cultured is on a swab, roll the swab over a small area of the agar surface. Streak for isolation with a sterile loop. If the specimen is collected on a loop or needle, inoculate the plate with fungi in two or three distinct places by pressing the inoculum onto the agar surface. Yeasts should be streaked for isolation using four quadrants.

4. Incubate plates in an inverted position. Consult listed references for more information on incubation time and temperature.[1,3,4,8] Once inoculated, media can be incubated aerobically at 25-35ºC. with increased humidity for four weeks or longer. Hardy Diagnostics MycoSeal™ product (Cat. no. SS9225) may be used to seal the plates to keep moisture from evaporating from the plated media, while still allowing atmospheric circulation

5. Examine plates for typical colonial and hyphal morphology and color.

Refer to the keyword "CSP Surface and Fingertip Monitoring - Contact Plates" on the Hardy Diagnostics Technical Document for more information regarding the method of use for Cat. no. P93, and P80 Contact Plates

INTERPRETATION OF RESULTS

Identification of fungi is performed by observing various aspects of colony morphology, characteristic microscopic structures, rate of growth, media which supports the organisms growth, and source of the specimen. Yeasts are identified by various biochemical tests. Consult the listed references for information regarding the identification and further testing of fungi and yeast cultures.[1,3,4,8]

LIMITATIONS

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.

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, other culture media, swabs, applicator sticks,

incinerators, and 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	
Malt Extract Agar: H57, P93, W28					
Aspergillus brasiliensis ATCC® 16404	G	2-7 days	15-30°C	Aerobic	Growth
Candida albicans ATCC® 10231	A	24-48hr	15-30°C	Aerobic	Growth
Saccharomyces cerevisiae ATCC® 9763	A	24-48hr	15-30°C	Aerobic	Growth
Malt Extract Agar with Chloramphenicol: L128, P80, W80					
Aspergillus brasiliensis ATCC® 16404	G	2-7 days	15-30°C	Aerobic	Growth
Candida albicans ATCC® 10231	A	24-48hr	15-30°C	Aerobic	Growth
Saccharomyces cerevisiae ATCC® 9763	A	24-48hr	15-30°C	Aerobic	Growth
Escherichia coli ATCC® 25922	B	24-48hr	35°C	Aerobic	Partial to complete inhibition

* Consult appropriate regulatory agency for user QC requirements.

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

USER QUALITY CONTROL

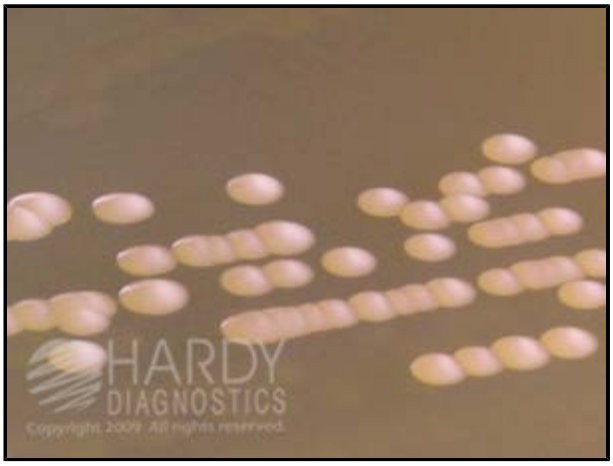
End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory 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

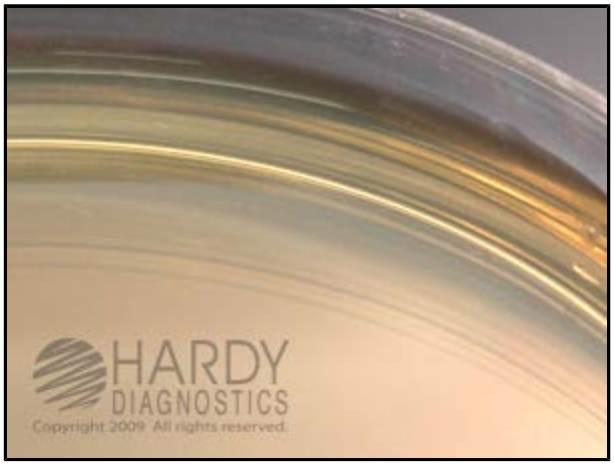
Malt Extract Agar should appear clear, slightly opalescent, and light to medium amber in color. A few small specks may be present in the media.

Aspergillus brasiliensis (ATCC® 16404) growing on Malt Extract Agar (Cat. no. W28). Incubated aerobically for 7 days at 30ºC.

Candida albicans (ATCC® 10231) colonies growing on Malt Extract Agar (Cat. no. W28). Incubated aerobically for 48 hours at 30ºC.



Saccharomyces cerevisiae (ATCC® 9763) colonies growing on Malt Extract Agar (Cat. no. W28). Incubated aerobically for 48 hours at 30ºC.



Uninoculated plate of Malt Extract Agar (Cat. no. W28).

REFERENCES

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2. Atlas, R.M. 1995. *Handbook of Microbiological Media for the Examination of Food*. CRC Press, Boca Raton, LA.

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4. APHA Technical Committee on Microbiological Methods for Foods. *Compendium of Methods for the Microbiological Examination of Foods,* APHA, Washington, D.C.

5. U.S. Food and Drug Administration. *Bacteriological Analytical Manual.* AOAC, Arlington, VA. http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm.

6. Ajello, et al. 1963. *CDC Laboratory Manual for Medical Mycology*, PHS Publication No. 994. U.S. Gov't Printing Office, Washington, D.C.

7. Thom, C. and M.B. Church. 1926. *The aspergilli.* Williams & Wilkins Co., Baltimore, MD.

8. U.S. Environmental Protection Agency. 2002. "A brief guide to mold, moisture, and your home." Internet: https://www.epa.gov/mold/brief-guide-mold-moisture-and-your-home.

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

HDQA 2207F [D]