IFU

Instructions for Use

MYCOVUE™ FUNGI CULTURE SYSTEM

Cat. no. MV1	MycoVue™ Potato Flake Agar	5 tests/pkg

Each unit contains:
1 Agar Block in a molded plastic container, covered by a plastic tab
1 Humidifying Chamber

1 Plastic Coverslip

1 Plastic Lid

INTENDED USE

Hardy Diagnostics MycoVue™ Fungi Culture Systems are prepared, ready-to-use, and disposable diagnostic devices for performing slide cultures for the identification of fungi.

SUMMARY

Historically, the identification of fungi has been accomplished by isolating organisms on appropriate solid culture media and observing their macroscopic and microscopic appearance. Colonial morphology may be of little value in the identification of filamentous fungi due to the natural variations among isolates that are culture media dependent. Instead, accurate identification of filamentous fungi is based on the microscopic examination of sporulating parts of a colony, since each species has a characteristic morphology and arrangement of its spores and fruiting bodies.

The best method for preserving and observing the actual structure of a fungus is the slide culture. It is unsurpassed as a routine means of studying the fine points of the microscopic morphology of fungi.[4] The conventional slide culture system is cumbersome and time consuming. Briefly, a plate of appropriate agar is prepared, and from this agar small blocks are aseptically cut, removed, and placed on a sterile slide. The agar is inoculated with the fungus to be identified, a sterile coverslip is placed on the top surface of the agar block, and the entire unit (slide and all) is placed in a petri dish on a supporting mechanism (usually a sterile bent glass rod). In the bottom of the petri dish, a piece of dampened blotting paper is placed. The lid is placed on the petri dish, and the slide culture is incubated for an appropriate amount of time. After inoculation, the coverslip is removed from the agar block and placed on another slide to which a dye, such as lactophenol cotton blue, may be added. Identification is made by microscopically examining the undisturbed sporulating structures as they were arranged during growth on the agar block under the coverslip.[3] There are many variations on this method, most requiring elaborate preparations.

While slide preparations are useful for identification, they have significant drawbacks. First, sporulating structures may be difficult to discern if:

1) Too much growth is removed,
2) The growth is not teased well,
3) The material is taken from a non-sporulating area of growth,

4) The disruption of spores during preparation of the mount may destroy the identifying arrangement of the
sporulating structures.[1]
5) It is difficult to know the optimal time when the fungal fruiting structures are mature enough to remove
the coverslip for microscopic examination.

The MycoVue™ Fungi Culture System provides the laboratorian with a standardized, comprehensive system that eliminates time-consuming preparations and technical difficulties encountered with the classical slide culture method.[2] It simplifies the slide culture by providing all the necessary components for this procedure in one ready-to-use, disposable unit. The device is designed to fit easily onto a microscope stage, thereby allowing direct viewing of the developing fungus through the device thus eliminating the disruption of the fungal colony. If desired, the lid of the device can be removed and the coverslip stained for further evaluation or preservation.

MycoVue™ Fungi Culture System is available in the following formulation:

- **Potato Flake Agar** - a general fungal medium that enhances sporulation.

FORMULA

Ingredients per liter of deionized water:*

MycoVue™ Potato Flake Agar (MV1):	
Potato Flakes	20.0gm
Glucose	10.0gm
Agar	15.0gm

Final pH 5.6 +/- 0.3 at 25ºC.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2 to 8ºC. 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

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.

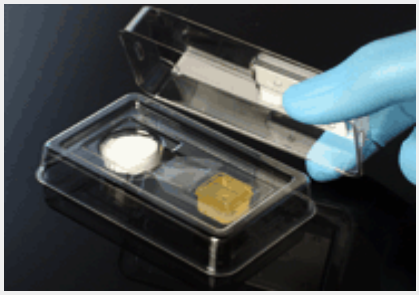
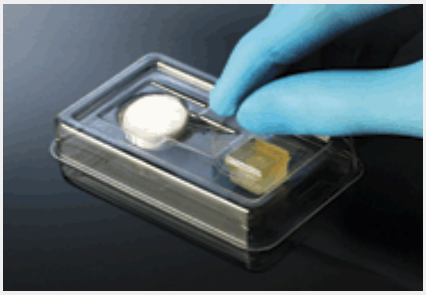
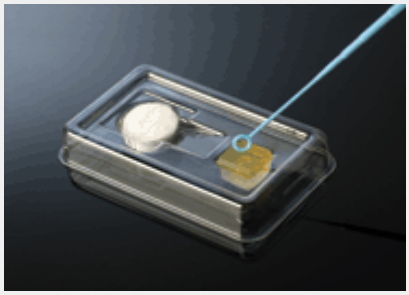
This product is for *in vitro* diagnostic use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions."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

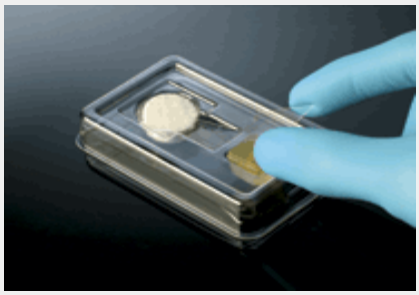
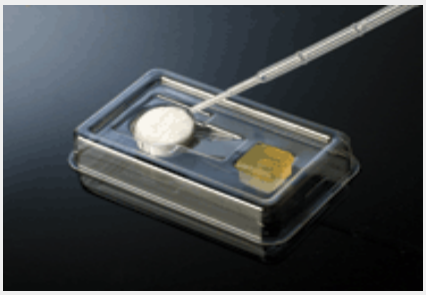
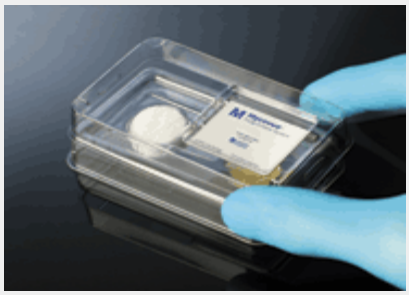
For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers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

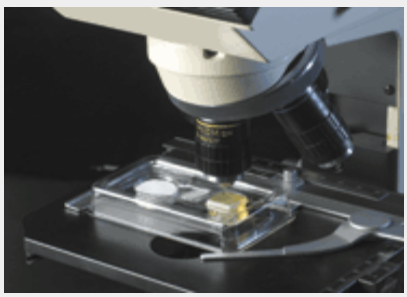
Sterilize all biohazard waste before disposal.

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

PROCEDURE

		
1. Remove lid from the device.	2. Carefully peel off the media cover tab and discard.	3. Inoculate the agar surface with the specimen.

		
4. Place the included sterile coverslip onto the inoculated agar surface.	5. Add approx. 1ml sterile water (Cat. no. K187) to the sponge.	6. Replace the lid of the device and incubate at 25ºC. (or room temperature).

	
7. To examine growth, remove cover and place unit on the microscope stage.	8. Alternatively, you may stain the fungal growth adhering to the coverslip by placing a drop of Lactophenol Cotton Blue (Cat. no. Z68) on a glass microscope slide. Remove the MycoVue™ coverslip and place it on the slide for viewing under the microscope. Replace the MycoVue™ coverslip with a new one. **Note:** For a permanent stain use BlueMount™ (Cat. no. Z137).

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 organism's growth, and source of the specimen. Consult the listed references for information regarding the identification and further testing of fungal and yeast cultures.[1,4,5]

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 microscope slides, loops, Sterile Water (Cat. no. K187), Lactophenol Cotton Blue (Cat. no. Z68), BlueMount™ (Cat. no. Z137), other culture media, swabs, microscopes, incinerators, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

USER QUALITY CONTROL

Check for signs of contamination and deterioration. Users of commercially prepared media may be required to perform quality control testing with organisms to demonstrate growth or a positive reaction; and at least one organism to demonstrate inhibition or a negative reaction (where applicable). Also see listed references for more information.[4,5]

PHYSICAL APPEARANCE

MycoVue™ Potato Flake Agar should appear slightly opaque, with a heavy precipitate, and white in color.

REFERENCES

1. Versalovic, J., et al. *Manual of Clinical Microbiology.* American Society for Microbiology, Washington, D.C.

2. Rollender, William. 1998. "*Innovative Slide Culture Test for the Identification of Fungi*", ASM, Atlanta, GA.

3. Mahon, C., Manuselis, G., Jr. 1995. *Textbook of Diagnostic Microbiology*, WB Saunders, Co., Philadelphia, PA, p. 691.

4. Larone, D.H. *Medically Important Fungi: A Guide to Identification,* American Society for Microbiology. Washington, D.C.

5. St. Germain, Guy, et al. 1996. *Identifying Filamentous Fungi*. Star Publishing Company, Belmont, CA.

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