



Instructions for Use

MODIFIED DIAMONDS MEDIUM

Cat. no. K02

Modified Diamonds Medium, 16x100mm Tube, 6ml

20 tubes/box

INTENDED USE

Hardy Diagnostics Modified Diamonds Medium is recommended as an enriched and selective medium for the isolation and cultivation of *Trichomonas* species from clinical specimens, especially *T. vaginalis*.

SUMMARY

The cultivation of *T. vaginalis* is the most sensitive method for the diagnosis of this sexually transmitted organism. Modified Diamonds Medium has been found to be an effective medium for the culture of this organism. The medium is enriched with yeast extract and supplemented with inactivated horse serum, amphotericin B, penicillin G, and gentamicin. Modified Diamonds Medium is formulated to allow trichomonads to grow, while suppressing bacterial growth. The addition of small amounts of agar reduces the oxygen tension, resulting in more prolific growth of trichomonads, which optimally grow and reproduce under anaerobic conditions.⁽⁸⁾ Culture medium techniques allow for a more accurate method for detecting *Trichomonas* species, and are an effective means of determining treatment efficacy.

FORMULA

Ingredients per 880ml of deionized water:*

Pancreatic Digest of Casein	15.0gm
Yeast Extract	12.0gm
Glucose	5.5gm
Sodium Chloride	2.5gm
L-Cystine	0.5gm
Sodium Thioglycollate	0.5gm
Gentamicin	80.0mg
Amphotericin B	2.0mg
Penicillin G	1,000,000U
Horse Serum	120.0ml
Agar	0.75gm

Final pH 7.0 +/- 0.3 at 25°C.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-8°C. away from direct light. Media should not be used if there are any signs of deterioration (evaporation 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 dating 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 quality control incubation times.

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 blood precautions. 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." The "Guidelines for Isolation Precautions" is available from the Centers for Disease Control and Prevention at www.cdc.gov/ncidod/dhqp/gl_isolation.html.

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 M-29: *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline*.

Sterilize all biohazard waste before disposal.

Refer to the document "[Precautions When Using Media](#)" for more information.

Refer to the document [SDS Search](#) instructions on the Hardy Diagnostics' website 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 into an appropriate transport medium, and kept at 30-35°C. until inoculation.

Method of Use: Allow the Modified Diamonds Medium to come to room temperature before inoculation.

Vaginal or urethral discharges and prostatic secretions collected at the time of examination may be used to inoculate the medium, which is then taken directly to the laboratory for incubation. Urine specimens or other inoculum with suspected low numbers should be centrifuged and the sediment used as inoculum. (Additionally, at the time of collection, a fresh wet smear should be examined microscopically for the presence of trophozoites). Consult appropriate references for further inoculation methods.⁽²⁻⁴⁾

Modified Diamonds Medium is inoculated by immersing the specimen in the medium, and gently twirling. Breaking the swab to leave in the medium is not necessary. Incubate with tight cap at 30-35°C. for 1-3 days. Examine the culture after 24 hours of incubation microscopically for the presence of trophozoites.* Aseptically remove a drop of the culture and place it on a slide and cover with a glass coverslip. Examine under 100x-400x magnification. If the organism is not seen, incubate the culture again for up to three days, examining daily or every other day in the same

manner. If after three days no trichomonads are seen, the specimen is considered negative.

*Specimens collected at an off site clinic, or delayed in transport to the laboratory can be examined after 2 days of incubation to increase sensitivity.

It is suggested to culture the patient one week after therapy is completed. If the culture is negative, a second culture is taken in two to four weeks. If this third culture is negative for the presence of trophozoites, treatment was effective.

INTERPRETATION OF RESULTS

The wet mount is examined under 100x-400x magnification, with phase contrast and/or differential interface contrast optics preferred. If motile trophozoites are observed between 7-23mm in size, the test is considered positive for *Trichomonas vaginalis*. If no trophozoites are seen after three days of incubation, discard and report as negative.

LIMITATIONS

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

Modified Diamonds Medium, is a selective medium and may, to some extent, inhibit the specific strains it is designed to grow. Other microorganisms may grow in this medium as microbial resistance to the antibiotics contained within this medium can occur.

Due to the fastidious nature of *T. vaginalis*, the culture will remain viable for a short period of time after reaching the stationary phase. The use of a daily wet mount preparation cannot be over emphasized to achieve consistently accurate results.

It is recommended to perform quality control on the media each week of testing. Positive controls should be subcultured every three to four days to maintain viability.

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, pasteur pipets, slides, coverslips, applicator sticks, incinerators, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

The microscope should be calibrated (within the last 12 months), and the objectives and oculars used for the calibration procedure should be in place on the microscope when objects are measured.⁽⁵⁾

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificates of Analysis (CofA). The following organisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
<i>Trichomonas vaginalis</i> Clinical strain	A	24-72hr	35°C	Aerobic	Growth; twitching motility seen microscopically at 10x-40x - wet mount

<i>Candida albicans</i> ATCC ® 10231	B	72hr	35°C	Aerobic	Inhibited
<i>Escherichia coli</i> ATCC ® 25922	B	72hr	35°C	Aerobic	Inhibited

* 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 certificates of analysis (CofA) available from Hardy Diagnostics [Certificates of Analysis](#) website. In addition, refer to the following document "[Finished Product Quality Control Procedures](#)," for more information on QC or see reference(s) for more specific information.

PHYSICAL APPEARANCE

Modified Diamonds Medium should appear clear, and light amber in color.



Trichomonas vaginalis (Clinical strain) growing in Modified Diamonds Medium (Cat. no. K02). Incubated aerobically for 96 hours at 35°C. Showing turbidity in lower portion of tube.

REFERENCES

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3. Tille, P., et al. *Bailey and Scott's Diagnostic Microbiology*, C.V. Mosby Company, St. Louis, MO.
4. Garcia, L.S. and D.A. Bruckner. 2007. *Diagnostic Medical Parasitology*, 5th ed. American Society for Microbiology, Washington, D.C.
5. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.

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7. Schmid, G.P., et al. 1989. Evaluation of six media for the growth of *Trichomonas vaginalis* from vaginal secretions. *J. Clin. Microbiol.*; 27:1230-1233.
8. Poch, F., et al. 1996. *Journal of Clinical Microbiology*; Vol. 34, No. 10, p. 2630-2631.
9. Gelbart, S.M., et al. 1990. *Journal of Clinical Microbiology*; Vol. 28, No. 5, p. 962-964.

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