IFU

Instructions for Use

THAYER MARTIN, MODIFIED

Cat. no. E30	Thayer Martin, Modified, 15x100mm Plate, 18ml	10 plates/bag
Cat. no. E130BX	Thayer Martin, Modified, with Vancomycin, 15x100mm Plate, 18ml	100 plates/box
Cat. no. E450	Thayer Martin, Modified, 50x75mm Square Pill Pocket Plate, 16ml	10 plates/bag
Cat. no. J72	Chocolate / MTM (Modified Thayer Martin), 15x100mm Biplate, 10ml/10ml	10 plates/bag

INTENDED USE

Hardy Diagnostics Modified Thayer Martin (MTM) is a selective medium used in qualitative procedures for the isolation of *Neisseria gonorrhoeae* with suppression of most other gram-negative diplococci, gram-negative bacilli, gram-positive organisms, and yeast.

SUMMARY

Thayer and Martin (1964) reported an improvement of the Chocolate Agar formulation by the addition of antimicrobics which suppressed the growth of some contaminating organisms but which allowed *N. gonorrhoeae* and *N. meningitidis* to grow. In 1970, trimethoprim lactate was shown to be of value in the suppression of *Proteus* spp. The resulting medium is called Modified Thayer Martin.

FORMULA

Ingredients per liter of deionized water:**

Proteose Peptone No. 3	15.0gm
Hemoglobin, Bovine	10.0gm
Sodium Chloride	5.0gm
Dipotassium Phosphate	4.0gm
Monopotassium Phosphate	1.0gm
Corn Starch	1.0gm
Colistin	7.5mg
Trimethoprim Lactate*	5.0mg
Vancomycin	3.0mg
Nystatin	1,250U
KoEnzyme Enrichments	10.0ml

Agar	12.0gm

Final pH 7.2 +/- 0.2 at 25ºC.

*Thayer Martin, Modified with Vancomycin (Cat. no. E130BX) does not contain Trimethoprim Lactate.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-8ºC. 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. 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

Specimen Collection: Specimens 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, specimens should be inoculated into an appropriate transport medium such as Amies with charcoal. Specimens must be transported at ambient temperatures (15-30 degrees C). Do not refrigerate. Refer to listed references for more information on specimen collection and transport.[1-3]

Method of Use: Bring media to room temperature before use. Inoculate media and streak to obtain isolated colonies. Incubate 24-48 hours at 35ºC. in 5-10% CO_2. Some strains may require up to 72 hours to appear.

Square Pill Pocket Plate: After inoculation, place one CO_2 tablet in the pill pocket and place plate in a sealed zip bag. Do not invert the plate. Proceed with incubation parameters as outlined above.

INTERPRETATION OF RESULTS

Neisseria gonorrhoeae appears as small, grayish-white to colorless mucoid colonies. *N. meningitidis* forms similar

colonies to *N. gonorrhoeae*, but larger and blue-gray.

An oxidase test may be performed from the primary medium for presumptive identification.

LIMITATIONS

Some diagnostic tests may be performed with the primary media. However, additional tests including gram stain and biochemical testing should be performed on pure cultures for complete identification. For more information, see appropriate references.

The agents in selective media may inhibit some strains of desired species or permit the growth of species they were designed to inhibit. Therefore, specimens cultured on selective media should also be cultured on non-selective media to obtain additional information and to help insure recovery of potential pathogens. Some strains of vancomycin-sensitive *N. gonorrhoeae* may be inhibited on this media. To avoid this inhibition, see "Martin Lewis with Lincomycin".

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	
Thayer Martin, Modified:					
Neisseria gonorrhoeae ATCC® 43069	A	24-48hr	35°C	CO_2**	Growth
Neisseria meningitidis ATCC® 13090***	A	24-48hr	35°C	CO_2**	Growth
Staphylococcus epidermidis ATCC® 12228	B	24-48hr	35°C	CO_2**	Partial to complete inhibition
Proteus mirabilis ATCC® 43071	B	24-48hr	35°C	CO_2**	Partial to complete inhibition; no swarming
Escherichia coli ATCC® 25922***	B	24-48hr	35°C	CO_2**	Partial to complete inhibition
Candida albicans ATCC® 60193***	B	24-48hr	35°C	CO_2**	Partial to complete inhibition
Neisseria sicca ATCC® 9913***	B	24-48hr	35°C	CO_2**	Inhibited

		Incubation			

Test Organisms	Inoculation Method*	Time	Temperature	Atmosphere	Results
Thayer Martin, Modified, with Vancomycin (Cat. no. E130BX):					
Neisseria gonorrhoeae ATCC® 43069	A	24-48hr	35°C	CO_2**	Growth
Neisseria meningitidis ATCC® 13090***	A	24-48hr	35°C	CO_2**	Growth
Staphylococcus epidermidis ATCC® 12228	B	24-48hr	35°C	CO_2**	Partial to complete inhibition
Escherichia coli ATCC® 25922***	B	24-48hr	35°C	CO_2**	Partial to complete inhibition
Candida albicans ATCC® 60193***	B	24-48hr	35°C	CO_2**	Partial to complete inhibition
Neisseria sicca ATCC® 9913***	B	24-48hr	35°C	CO_2**	Inhibited

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

** Atmosphere of incubation is enriched with 5-10% CO_2.

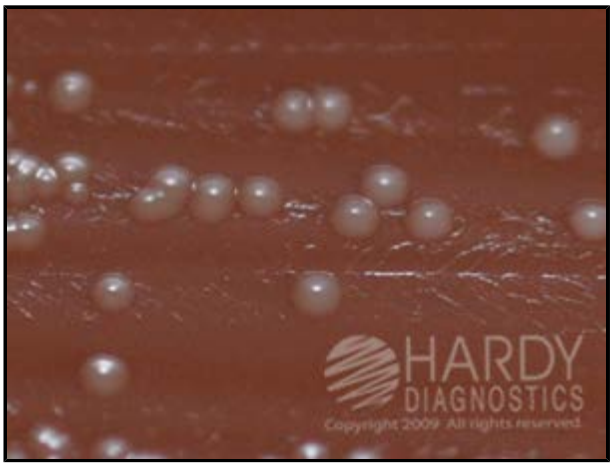
*** To be used only by commercial media manufacturers.

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

Thayer Martin, Modified Agar should appear opaque, and brown in color.



Neisseria gonorrhoeae (ATCC® 43069) colonies growing on

Staphylococcus epidermidis (ATCC® 12228) growth inhibited on

Thayer Martin, Modified Agar (Cat. no. E30). Incubated in CO_2 for 48 hours at 35ºC.

Thayer Martin, Modified Agar (Cat. no. E30). Incubated in CO_2 for 48 hours at 35ºC.

REFERENCES

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

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

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

4. 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.

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

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

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