IFU

Instructions for Use

TRANSGROW

Cat. no. X52	Transgrow, 50ml HardyFlask™, 12ml	20 flasks/box

INTENDED USE

Modified Martin Lewis 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. The CO_2 enriched environment allows for the growth of pathogenic *Neisseria* spp.

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. Martin and Lester modified Thayer-Martin Agar by increasing the dextrose concentration for transport, in addition to adding trimethoprim lactate. Martin and Lewis further improved the ability of the medium to inhibit *Candida albicans* by substituting anisomycin for nystatin. Because of the growing number of vancomycin strains of *N. gonorrhoeae* , the vancomycin concentration was reduced to 3mcg/ml, which resulted in the current formula for Modified Martin-Lewis Media. Hardy Diagnostics Transgrow incorporates adequate CO_2 within the media bottle to provide an enriched atmosphere for the recovery of pathogenic *Neisseria* spp.[6]

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
Dextrose	1.5gm
Monopotassium Phosphate	1.0gm
Corn Starch	1.0gm
Anisomycin	10.0mg
Colistin	7.5mg
Trimethoprim Lactate	5.0mg
Vancomycin	3.0mg

KoEnzyme Enrichments	10.0ml
Agar	12.0gm

Final pH 7.3 +/- 0.2 at 25ºC.

* 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), 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: If the bottle is to be sent to a laboratory after inoculation, incubate them under appropriate conditions before shipment. Specimens should be submitted directly to the laboratory without delay and protected from excessive heat and cold. Specimens must be transported at ambient temperatures (15-30ºC.). Do not refrigerate.

Method of Use: Bring media to room temperature before use. Remove the cap while holding the bottle in the upright position. **The bottle must always be held in the upright position when the cap is off.** The CO_2 gas, which is necessary for growth, is heavier than air and will leak out of the bottle if it is tilted. Inoculate media by swabbing the surface from side to side (starting at the bottom) while rolling in a large "z" pattern to sufficiently transfer the specimen. Recap the bottle immediately. Do not leave the cap off any longer than necessary. Incubate at 35ºC. for 24-48 hours. Some strains may require up to 72 hours to appear.

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

This medium is intended for transport and primary isolation. 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.[1-4]

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.[1-3]

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	
Neisseria gonorrhoeae ATCC® 43069	A	24-48hr	35°C	CO_2**	Growth
Neisseria gonorrhoeae ATCC® 19424	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

* 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.

** CO_2 enriched atmosphere is generated within the bottle.

*** To be used only by commercial media manufacturers, according to NCCLS document M22-A.

PHYSICAL APPEARANCE

Transgrow should appear opaque, and brown in color.

Neisseria gonorrhoeae (ATCC® 43069) colonies growing on Transgrow (Cat. no. X52). Incubated in CO_2 for 48 hours at 35ºC.

Staphylococcus epidermidis (ATCC® 12228) growth inhibited on Transgrow (Cat. no. X52). Incubated in CO_2 for 48 hours at 35ºC.

REFERENCES

1. Jorgensen., 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.

6. Potter, L.D., et al. 1983. Ammonium bicarbonate as a replacement for carbon dioxide in Transgrow bottles for primary isolation of *Neisseria gonorrhoeae*. *J. Clin. Microbiol.*; 18:1258-1259.

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

HDQA 2207F [D]