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Instructions for Use

MARTIN LEWIS AGAR WITH LINCOMYCIN, PILL POCKET

Cat. no. E31	Martin Lewis with Lincomycin, 15x100mm Pill Pocket Plate, 24ml	10 plates/bag

INTENDED USE

Hardy Diagnostics Martin Lewis with Lincomycin is a selective medium for the recovery of *Neisseria gonorrhoeae* from both genital and oropharyngeal specimens. It is 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

Several successive media have been developed for the isolation of pathogenic *Neisseria* from specimens containing mixed flora. Each successive formula, Thayer Martin Selective Agar, Modified Thayer Martin and Martin Lewis Agar, provides greater inhibition of contaminating flora, however, each has been shown to be inhibitory to certain vancomycin sensitive strains of *Neisseria* spp.

Martin Lewis with Lincomycin provides a rich, selective growth media with decreased vancomycin. These plates are supplied with a CO_2 tablet (sodium bicarbonate and citric acid) that fits into a molded well in the petri dish. When sealed inside the ziplock bag, moisture in the air slowly activates the tablet to produce a CO_2 enriched atmosphere that is conducive to the growth of gonococci.

FORMULA

Ten CO_2 generating tablets (sodium bicarbonate and citric acid) and 10 ziplock bags are included with each bag of Martin Lewis with Lincomycin, Pill Pocket media.

Ingredients per liter of deionized water:*

Hemoglobin, Bovine	10.0gm
Pancreatic Digest of Casein	7.5gm
Selected Meat Peptone	7.5gm
Sodium Chloride	5.0gm
Dipotassium Phosphate	4.0gm
Monopotassium Phosphate	1.0gm
Corn Starch	1.0gm
Colistin	7.5mg

Trimethoprim Lactate	5.0mg
Amphotericin B	1.5mg
Vancomycin	1.0mg
Lincomycin	1.0mg
Koenzyme Enrichments	10.0ml
Agar	10.0gm

Final pH 7.2 +/- 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. away from direct light. 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

Method of Use: Bring media to room temperature before use. Inoculate media by swabbing the surface from side to side while rolling in a large "z" pattern to sufficiently transfer the specimen. Remove the CO_2 generating tablet from the foil wrapper and immediately place the tablet into the circular well of the petri plate. The tablet will be activated by the moisture in the medium. **Do not place a drop of water on the tablet.** There is adequate moisture generated in the bag to slowly release the CO_2. Place the plate in the ziplock bag and seal. The completeness of the seal is essential to maintain CO_2 environment for growth. Invert plates and incubate at 35ºC. for 24-48 hours. Some strains may require up to 72 hours to appear.

If the plate 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.

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.

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.

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 meningitidis ATCC® 13090***	A	24-48hr	35°C	CO_2**	Growth
Proteus mirabilis ATCC® 43071	B	24-48hr	35°C	CO_2**	Partial to complete inhibition; no swarming
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.

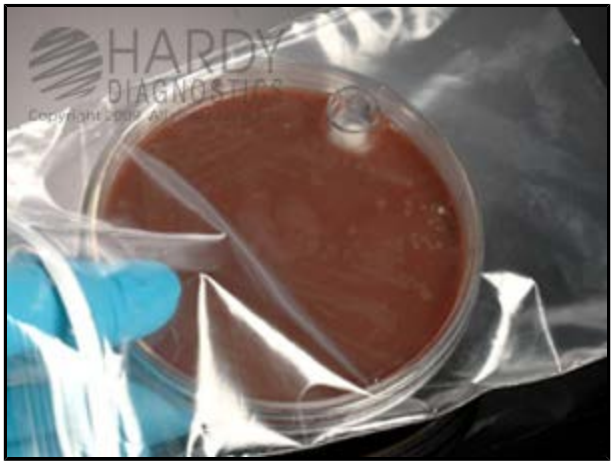
USER QUALITY CONTROL

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

Martin Lewis with Lincomycin, Pill Pocket should appear opaque, and smooth brown in color.

Neisseria gonorrhoeae (ATCC® 43069) colonies growing on Martin Lewis Agar with Lincomycin, Pill Pocket (Cat. no. E31). Incubated in CO_2 for 48 hours at 35ºC.



Shown with ziplock bag and CO_2 tablet.
Neisseria gonorrhoeae (ATCC® 43069) colonies growing on Martin Lewis Agar with Lincomycin, Pill Pocket (Cat. no. E31). Incubated in CO_2 for 48 hours at 35ºC.

Proteus mirabilis (ATCC® 43071) growth inhibited on Martin Lewis Agar with Lincomycin, Pill Pocket (Cat. no. E31). 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.

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

HDQA 2207F [D]