REF 42 041

Portagerm pylori (PORT-PYL)

Specific transport medium for H. pylori

SUMMARY AND EXPLANATION

This medium is for the transport of gastric biopsies with a view to their culture for the detection of *Helicobacter pylori* (1, 2, 4).

It provides the optimum conditions necessary to maintain the viability of these organisms (3).

PRINCIPLE

Portagerm pylori is a semi-agar medium combining:

- a buffered peptone base,
- elements favoring the maintenance of H. pylori,
- a mixture of antibiotics limiting the proliferation of organisms from the oropharyngeal flora withdrawn on gastroscopy.

CONTENT OF THE KIT

Ready-to-use medium

REF 42 041 8 x 2.5 ml bottles

1 package insert provided in the kit or downloadable from www.biomerieux.com/techlib

COMPOSITION

Theoretical formula

This medium can be adjusted and/or supplemented according to the performance criteria required:

Casein peptone (bovine)	10 g
Soy peptone	8 g
Starch	2 g
Sodium chloride	7 g
Disodium phosphate	2.5 g
Agar	6 g
Antibiotic mixture	20 ml
Purified water	11

pH 6.3

MATERIAL REQUIRED BUT NOT PROVIDED

• Pylori agar (Ref. 43 263).

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- For professional use only.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).

- All specimens, microbial cultures and inoculated products should be considered infectious and handled appropriately. Aseptic technique and usual precautions for handling the bacterial group studied should be observed throughout this procedure. Refer to "CLSI® M29-A, Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Current Revision". For additional information on handling precautions, refer to "Biosafety in Microbiological and Biomedical Laboratories - CDC/NIH - Latest edition", or the current regulations in the country of use.
- Do not use reagents after the expiry date.
- Do not use bottles that show signs of contamination.
- Before use, check that the bottle cap is intact.
- The performance data presented were obtained using the procedure indicated in this package insert. Any change or modification in the procedure may affect the results.

STORAGE CONDITIONS

• The bottles can be stored in their box at 2-8°C until the expiration date.

SPECIMENS

The medium is intended for the transport of gastric biopsies.

INSTRUCTIONS FOR USE

Introduction of the sample:

- 1. Allow the bottle to come to room temperature.
- 2. Plunge the specimen deeply into the agar immediately after collection.

Processing of the bottles in the laboratory:

- 1. Transport the bottles to the laboratory, protected from light, as rapidly as possible after specimen collection.
- 2. Extract the sample from the bottle using a loop, for example.
- 3. Inoculate immediately onto a specific medium (Pylori agar). For the inoculation procedures, refer to the package insert for this product.

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QUALITY CONTROL

Protocol:

The performance of the medium can be tested using the following strain:

- Helicobacter pylori ATCC[®] 43504
- 1. Prepare a suspension of the strain in sterile physiological saline.
- 2. Introduce 0.25 ml of this suspension into a bottle and mix gently with the agar, avoiding the formation of bubbles.
- 3. Store the bottle at 20-25°C, away from light, for 48 hours.
- 4. Subculture a loopful on the pylori agar.
- 5. Incubate for 7 days in a microaerophilic atmosphere at 33-37°C.

Range of expected results:

Strain	Results after storage at 20-25°C
Helicobacter pylori ATCC [®] 43504	Growth

Note:

It is the responsibility of the user to perform Quality Control taking into consideration the intended use of the medium, and in accordance with any local applicable regulations (frequency, number of strains, incubation temperature, etc.).

LIMITATIONS OF THE METHOD

The presence of a precipitate in the Portagerm pylori medium does not affect the performance of the medium.

PERFORMANCE

Performance was evaluated at 25°C using 13 bacterial strains, including 7 strains of *H. pylori* and 1 yeast strain (*Candida*).

Results

The Portagerm pylori medium maintained the viability of the 7 strains of *H. pylori* for 48 hours.

After storage for 48 hours, 3 of the 6 bacteria tested other than *H. pylori* were inhibited.

The yeast was not inhibited after the storage period.

WASTE DISPOSAL

Unused reagents may be considered as non hazardous waste and disposed of accordingly. Dispose of all used reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.

It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

LITERATURE REFERENCES

- MEGRAUD F. Méthodes de diagnostic dans l'infection à Campylobacter pylori - Méd. et Mal. Inf., 1989, vol. 19, p. 74-78.
- 2. BUCK G.E. Campylobacter pylori and Gastroduodenal Disease Clin. Microbiol. Rev., 1990, vol. 3, n°1, p. 1-12.
- SEVIN E., SOUSSY C.J., TANKOVIC J. Helicobacter pylori en 1998 – Feuillets de Biologie, 1998, vol. 34, n°224, p. 15-30.
- MAROYE P. Diagnostic biologique de l'infection à Helicobacter pylori - Rev. Fr. Lab., Oct. 1999, vol. 316, p. 47-54.

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Temperature limitation
\Box	Use by
LOT	Batch code
(i-i-i)	Consult Instructions for Use
Σ	Contains sufficient for <n> tests</n>

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bioMérieux SA 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France

673 620 399 RCS LYON Tél. 33 (0)4 78 87 20 00 Fax 33 (0)4 78 87 20 90 www.biomerieux.com CE