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Instructions for Use

CARBOFERM™ NEISSERIA KIT

Cat. no. Z98	CarboFerm™ Neisseria Kit	24 tests/kit
	Each kit contains:	
	8-Well Reaction Strips	24 strips
	Color Reaction Reader	1 reader
	Reaction Worksheets	24 sheets
	Inoculation Buffer	24 tubes

INTENDED USE

Hardy Diagnostics CarboFerm™ Neisseria Kit is a rapid test (four hour) for the identification of *Neisseria* species (including *N. gonorrhoeae* and *N. meningitidis*) and *Moraxella* (*Branhamella*) *catarrhalis* . CarboFerm™ uses acid production from carbohydrates and the presence of butyrate esterase to differentiate and identify *Neisseria* species and *M. catarrhalis*.

SUMMARY

The majority of *Neisseria* species are considered normal flora of mucous membranes on humans. *Neisseria gonorrhoeae* is a sexually transmitted pathogen and *Neisseria meningitidis* is often associated with meningitis as well as colonization of the nasopharynx. *M. catarrhalis* causes respiratory tract and other infections.

Neisseria species have traditionally been identified by acid production from carbohydrates. CarboFerm™ Neisseria Kit reduces the time required to determine acid production to four hours (from the usual 48 hours). CarboFerm™ Neisseria Kit rapidly identifies *N. gonorrhoeae* , *N. meningitidis* , and *M. catarrhalis* , as well as other *Neisseria* species which may be normal flora (*N. lactamica, N. sicca*).

Clinical Laboratory Standards Institute (CLSI - formerly NCCLS) recommends using the butyrate esterase test to identify *M. catarrhalis.*[9]

FORMULA

Ingredients per liter of deionized water:*

CarboFerm™ Medium Base (well A)	
Peptone	2.0gm
Sodium Chloride	1.0gm
Beef Extract	0.6gm

Phenol Red	28.0mg

In addition, the following wells are supplemented with a specific carbohydrate:
Glucose (wells in row C)
Maltose (wells in row D)
Lactose (wells in row E)
Sucrose (wells in row F)

Final pH 6.9 +/- 0.1 at 25ºC.

Well H contains Bromo-Chloro-Indolyl-Butyrate, in an organic solvent, impregnated on a paper disk.

CarboFerm™ Inoculation Buffer	
pH Buffers	6.0gm

Final pH 6.9 +/- 0.1 at 25ºC.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2 to 8ºC. away from direct light. The kit should not be used if there is any discoloration or if the expiration date has passed. Do not use if desiccant is missing or if lids have been removed. 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: This product is not intended for primary isolation of patient specimens.

The appropriate organisms for performing the CarboFerm™ Neisseria test are oxidase-positive, gram-negative diplococci.

Method of use:

1. Remove caps from the test strips to be used. Leave strips in the base. Unused strips may be removed from the base and stored in the bag (with caps on) until needed.

2. Use a sterile swab or loop to transfer a pure isolate (from Chocolate, Thayer Martin, or Martin Lewis agar) into a tube of Inoculation Buffer. The culture should be no older than 24 hours. Prepare a heavy suspension (equivalent to a 4.0 McFarland turbidity standard or higher). Vortex and/or aspirate repeatedly until density of the solution is uniform in appearance. A low density may result in false-negative reactions.

3. Aseptically transfer 4 to 5 drops (or approximately 0.18ml) of the suspension into each well of the strip. **Do not add any suspension to the second (B) or seventh (G) wells.** These wells are intentionally left empty. Do not remove the test strips from the base holder.

4. Incubate strips uncovered at 35ºC. aerobically. Do not incubate in a CO_2 atmosphere. Read the butyrate well (row H) after 10 to 15 minutes. Read the carbohydrate wells (row A, C, D, E, and F) after four hours and before seven hours (some positives will appear in as little as two hours).

INTERPRETATION OF RESULTS

The reaction in row H (butyrate) should be read after 10 to 15 minutes at 35ºC. A blue coloration is considered positive.
Note: Color changes that take place in the butyrate well (H) after 15 minutes of incubation time should be disregarded.

Positive reactions can be read in as little as two hours. Negative carbohydrate wells should be held for a minimum of four hours. A change of color from red to orange or yellow is considered positive for the carbohydrate wells (wells C through F). Well A is used as a reference and should remain negative (red) throughout incubation, since it contains no carbohydrate. Read final results at four hours.
Note: Color changes in the carbohydrate wells that take place after seven hours of incubation time should be disregarded.

A carbohydrate reaction which is more yellow or orange than the control well (A) is considered positive.

Use the chart below to identify the listed organisms.

Organism	Negative Control (well A)	Glucose (well C)	Maltose (well D)	Lactose (well E)	Sucrose (well F)	Butyrate (well H)
*N. gonorrhoeae / cinerea**	- red	+ orange or yellow	- red	- red	- red	- white
N. meningitidis	- red	+ orange or yellow	+ orange or yellow	- red	- red	- white
	-	+	+	+	-	-

N. lactamica	red	orange or yellow	orange or yellow	orange or yellow	red	white
*N. sicca / N. mucosa***	- red	+ orange or yellow	+ orange or yellow	- red	+ orange or yellow	- white
M. catarrhalis	- red	- red	- red	- red	- red	+ blue

* Some strains of *N. cinerea* can be weakly positive for glucose. This has not been observed with CarboFerm™. Note that *N. cinerea* will not usually grow on Thayer Martin Agar (since it is usually sensitive to colistin) but will grow on Nutrient Agar. *N. gonorrhoeae* will grow on Thayer Martin Agar (Cat. no. E30) but will not grow on Nutrient Agar (Cat. no. L20).

** To distinguish between *N. sicca* and *N. mucosa* , perform a nitrate reduction test (Cat. no. K42). *N. mucosa* is positive for nitrate reduction and *N. sicca* is negative.

LIMITATIONS

This product is intended for pure cultures of oxidase-positive, gram-negative diplococci.

Some strains may give a weak positive reaction which is seen as an orange color in the wells containing carbohydrates or a pale blue in the butyrate well. Carbohydrate reactions should be considered positive if and only if the well containing the carbohydrate is more orange/yellow than the negative control well (row A).

Butyrate reactions should be read within 15 minutes or erroneous results may occur.

False-negatives may result from using too small of an inoculum, or old cultures (greater than 48 hours).

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, culture media, transfer pipettes, 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:

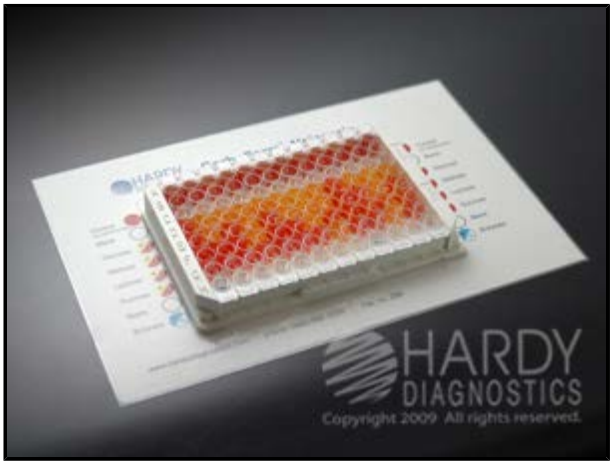
Test Organisms	Well	Incubation			Results
		Time	Temperature	Atmosphere	
N. gonorrhoeae ATCC® 43069	Control Glucose Maltose Lactose Sucrose Butyrate	4hr 4hr 4hr 4hr 4hr 10-15min	35°C	Aerobic	Red Positive, yellow/orange Negative, red Negative, red Negative, red Negative, white

N. meningitidis ATCC® 13090	Control Glucose Maltose Lactose Sucrose Butyrate	4hr 4hr 4hr 4hr 4hr 10-15min	35°C	Aerobic	Red Positive, yellow/orange Positive, yellow/orange Negative, red Negative, red Negative, white
N. lactamica ATCC® 23970	Control Glucose Maltose Lactose Sucrose Butyrate	4hr 4hr 4hr 4hr 4hr 10-15min	35°C	Aerobic	Red Positive, yellow/orange Positive, yellow/orange Positive, yellow/orange Negative, red Negative, white
N. sicca ATCC® 9913	Control Glucose Maltose Lactose Sucrose Butyrate	4hr 4hr 4hr 4hr 4hr 10-15min	35°C	Aerobic	Red Positive, yellow/orange Positive, yellow/orange Negative, red Positive, yellow/orange Negative, white
M. catarrhalis ATCC® 25240	Control Glucose Maltose Lactose Sucrose Butyrate	4hr 4hr 4hr 4hr 4hr 10-15min	35°C	Aerobic	Red Negative, red Negative, red Negative, red Negative, red Positive, blue

Check for signs of deterioration. It is recommended that users perform quality control testing with known organisms to demonstrate a positive reaction and a negative reaction.

PHYSICAL APPEARANCE

- Un-inoculated strips: Dehydrated wells A, C, D, E, and F should appear yellow to orange (wells will be red upon inoculation).
- Well H should contain a white disk.
- Wells B and G should be empty.
- Inoculation Buffer should appear clear and colorless.



CarboFerm™ Neisseria Kit (Cat. no. Z98).

Showing all results for the CarboFerm™ Neisseria Kit (Cat. no. Z98).

Showing results for *Neisseria gonorrhoeae* (ATCC® 43069) with the CarboFerm™ Neisseria Kit (Cat. no. Z98).

Showing results for *Neisseria meningitidis* (ATCC® 13090) with the CarboFerm™ Neisseria Kit (Cat. no. Z98).

Showing results for *Neisseria lactamica* (ATCC® 23970) with the CarboFerm™ Neisseria Kit (Cat. no. Z98).

Showing results for *Neisseria sicca* (ATCC® 9913) with the CarboFerm™ Neisseria Kit (Cat. no. Z98).

Showing results for *Branhamella (Moraxella) catarrhalis* (ATCC® 25240) with the CarboFerm™ Neisseria Kit (Cat. no. Z98). Note that the first well is blue.

REFERENCES

1. 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.

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

3. Berger, U. 1962. Uber die spaltung von tributyrin durch Neisseria. *Arch Hyg. Bakteriol.*; 146:388-391.

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

5. Janda, W.M. and P. Ruther. 1989. B. CAT CONFIRM; A rapid test for confirmation of *Branhamella catarrhalis*. *J. Clin. Microbiol.*; 27:1390-1391.

6. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology*, J.B. Lippincott Company, Philadelphia, PA.

7. Jorgensen., et al. *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, D.C.

8. Perez, J.L., et al. 1990. Butyrate esterase (tributyrin) spot test, a simple method for immediate identification of *Moraxella* (*Branhamella*) *catarrhalis*. *J. Clin. Microbiol.*; 28: 2347-2348.

9. *Abbreviated Identification of Bacteria and Yeast*; Approved Guideline, M35A, Vol. 22, No. 18. 2002. Clinical Laboratory Standards Institute (CLSI - formerly NCCLS), Villanova, PA.

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

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