api® NH

IVD

System for the identification of *Neisseria* and *Haemophilus*

SUMMARY AND EXPLANATION

API NH® is a standardized system for the identification of *Neisseria*, *Haemophilus* (and related genera) and *Moraxella catarrhalis* (*Branhamella catarrhalis*), which uses miniaturized tests, as well as a specially adapted database. The complete list of those organisms that it is possible to identify with this system is given in the Identification Table at the end of the package insert. API NH also enables the biotyping of *Haemophilus influenzae* and *Haemophilus parainfluenzae,* as well as the detection of a penicillinase.

PRINCIPLE

The API NH strip consists of 10 microtubes containing dehydrated substrates, which enable the performance of 12 identification tests (enzymatic reactions or sugar fermentations), as well as the detection of a penicillinase (particular interest in *Haemophilus influenzae, Haemophilus parainfluenzae, Moraxella catarrhalis* (*Branhamella catarrhalis*) and *Neisseria gonorrhoeae*).

During incubation, metabolism produces color changes that are either spontaneous or revealed by the addition of reagents.
The reactions are read according to the Reading Table and the identification is obtained by consulting the profile list in the package insert or using the identification software.

CONTENT OF THE KIT (Kit for 10 Tests)

- 10 API NH strips (STR)
- 10 ampules of API NaCl 0.85 % Medium (2 mL) (MED)
- 1 ampule of JAMES reagent (R1) solvent + 1 bottle of JAMES (R2) reagent (JAMES)
- 1 ampule of ZYM B (R1) solvent + 1 bottle of ZYM B (R2) reagent (ZYMB)
- 10 incubation boxes (INCUB)
- 10 result sheets (SHEET)
- 1 package insert provided in the kit or downloadable from **www.biomerieux.com/techlib**

COMPOSITION

Strip

The composition of the API NH strip is given in the Reading Table of this package insert.

Medium

API NaCl 0.85% Medium 2 mL	Sodium chloride Demineralized water	8.5 g 1000 mL

Reagents

JAMES reagent* 5 mL	R1: HCl 1N R2: Compound J 2183	100 mL 0.66 g

ZYM B (R1) ** solvent 5 mL	Methanol Dimethylsulfoxide (DMSO)	30 mL 70 mL
ZYM B (R2) * reagent**	Fast Blue BB (active ingredient)	0.14 g

The quantities indicated may be adjusted depending on the titer of the raw materials used.

* Signal word: **WARNING**

Hazard statement

H315: Causes skin irritation.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.

Precautionary statement

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

** Signal word: **DANGER**

Hazard statement

H226: Flammable liquid and vapour.
H302: Harmful if swallowed.
H311: Toxic in contact with skin.
H331: Toxic if inhaled.
H370: Causes damage to organs.

Precautionary statement

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P301 + P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

*** Signal word: **WARNING**

Hazard statement

H302: Harmful if swallowed.
H351: Suspected of causing cancer.

Precautionary statement

P280: Wear protective gloves/protective clothing/eye protection/face protection.
P301 + P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P308 + P313: IF exposed or concerned: Get medical advice/attention.

For more detailed information consult the material safety data sheet

REAGENTS AND MATERIAL REQUIRED BUT NOT PROVIDED

Reagents / Instrumentation

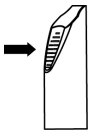
- McFarland Standard (Ref. 70 900), point 4 on the scale
- Mineral oil (Ref. 70 100)
- **api*web*™** identification software (Ref. 40 011), ATB ™ instrument or ***mini API*®** (consult bioMérieux)

Material

- Swabs
- Pipettes or PSIpettes
- Ampule rack
- Ampule protector
- General microbiology laboratory equipment

WARNINGS AND PRECAUTIONS

- **For *in vitro* diagnostic use and microbiological control.**
- **For professional use only.**
- Refer to the hazard statements “H” and precautionary statements “P” indicated above.
- 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 handling precautions, refer to "Biosafety in Microbiological and Biomedical Laboratories - CDC/NIH - Latest edition", or to the regulations currently in use in each country.
- Do not use reagents after the expiry date.
- Before use, check that the packaging and components are intact.
- Do not use strips which have been damaged : cupules deformed, desiccant sachet open, etc.
- Open ampules carefully as follows:
  - Place the ampule in the ampule protector.
  - Hold the protected ampule in one hand in a vertical position (white plastic cap uppermost).
  - Press the cap down as far as possible.
  - Position the thumb tip on the striated part of the cap and press forward to snap off the top of the ampule.
  - Take the ampule out of the ampule protector and put the protector aside for subsequent use.



* *For ampule with no dropper-cap:*
- Carefully remove the cap.

- 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.
- Interpretation of the test results should be made taking into consideration the patient history, the source of the specimen, colonial and microscopic morphology of the strain and, if necessary, the results of any other tests performed, particularly the antimicrobial susceptibility patterns.

STORAGE CONDITIONS

Strips STR

The strips should be stored at 2-8°C until the expiry date indicated on the packaging.

Media MED

The media may be stored at 2-30°C until the expiry date indicated on the packaging.

Reagents

The reagents should be stored in the dark at 2-8°C until the expiration date indicated on the packaging.
The JAMES reagent may be kept for up to 1 month after the ampules have been opened and the reagents reconstituted in the dropper-vial (or until the expiry date if this comes first): **record the opening date on the bottle label**.
The ZYM B reagent may be kept for up to 2 weeks after the ampules have been opened and the reagents reconstituted in the dropper-vials (or until the expiry date if this comes first): **record the opening date on the bottle label**.
The ZYM B and JAMES reagents are very sensitive to light : check the appearance of the JAMES reagent after reconstitution in the dropper-vials and check the appearance of the ZYM B reagent after reconstitution in the dropper-vial.
After reconstitution, the ZYM B reagent is normally yellow to amber in color.
After transferring the contents of the ampules into the dropper-vials, wrap the bottles of JAMES reagents in aluminium foil.

Make sure that the reagents are put back in the refrigerator immediately after use.

USE OF THE REAGENTS

1. ZYM B Reagent:

- Open the ampule of ZYM B (R1) solvent as indicated in the paragraph "Warnings and Precautions" (ampule with no dropper-cap) and transfer the content in the bottle of ZYM B (R2) reagent.
- Carefully close the bottle after use and store it as indicated in the paragraph "Storage conditions".

2. JAMES Reagent:

- Open the ampule of solvent associated with the JAMES reagent (R1) as indicated in the paragraph "Warnings and Precautions" (ampule with no dropper-cap).
- Take up the content of the ampule using a completely dry pipette and transfer this solvent into the dropper-bottle (R2).
- Fit the dropper to the bottle.
- Carefully close the bottle.
- Shake the bottle containing the dehydrated active ingredient.
- Wait approximately 10 minutes until the active ingredient is completely dissolved.
- Use the reagent thus reconstituted, carefully close the bottle and store it as indicated in the paragraph "Storage conditions".

NOTE: The JAMES reagent must only be used if it is pale yellow. If a pink color appears when the reagent is reconstituted with the solvent, wait until this pink color has completely disappeared before using the reagent.

SPECIMENS

API® NH is not for use directly with clinical or other specimens.
The microorganisms to be identified must first be isolated on a suitable culture medium according to standard microbiological techniques.

INSTRUCTIONS FOR USE
Selection of Colonies

Check that the strain to be studied belongs to the genera :
- *Neisseria* (Gram-negative cocci often joined in pairs). *Moraxella catarrhalis* (*Branhamella catarrhalis*) displays the same morphological and physiological characteristics.
- *Haemophilus* and related genera (small polymorphic and nutritionally-demanding Gram-negative rods).

These bacteria have demanding nutritional requirements and are usually cultivated on chocolate agar with PolyViteX ™ in a CO_2-enriched atmosphere.

As the API NH procedure requires an inoculum adjusted to 4 McFarland, it is generally necessary to perform a subculture. The following media may be used to culture the colonies before using the API® NH strip:
- chocolate agar with PolyViteX or derivative (Thayer Martin Medium), with or without antibiotic.
- blood agar media (Columbia, Trypticase-Soy, New York City Medium) may also be used, although the strength of certain biochemical reactions is modified. (This should be taken into account when reading the reaction).
- if other media are used for the isolation, perform a subculture on one of the previously mentioned media.
- The incubation of the subculture should be carried out **in a CO_2-enriched atmosphere** for 18-24 hours at 36°C ± 2°C (in order to obtain optimal enzymatic expression of the bacteria with the API® NH strip).

NOTE: Bacteria requiring appropriate handling precautions (e.g., *Brucella*, *Francisella*) are not included in the API NH database. Alternative procedures must be used to either confirm or exclude their presence.

Preparation of the Strip

- Prepare the incubation box (tray and lid).
- Record the strain reference on the elongated flap of the tray. (Do not record the reference on the lid as it may be misplaced during the procedure).
- Remove the strip from its individual packaging.
- Place the strip in the incubation box.
- Discard the desiccant sachet.

Preparation of the Inoculum

- Open an ampule of API® NaCl 0.85% Medium (2 mL) as indicated in the paragraph "Warnings and Precautions" (ampule with no dropper-cap).
- Using a swab, pick up a few well-isolated colonies and prepare a suspension with a turbidity equivalent to **4 McFarland**, **ensuring it is well mixed**. It is recommended to use young cultures (18-24 hours old).

This suspension must be used immediately after preparation.

Inoculation of the Strip

- Distribute the prepared bacterial suspension into the cupules, avoiding the formation of bubbles (tilt the strip slightly forwards and place the tip of the pipette or PSIpette against the side of the cupule):

- Only fill the tube part of the first 7 microtubes (PEN to URE): about 50 µl.
- Fill tube and cupule of the last 3 microtubes LIP/ProA, PAL/GGT, ßGAL/IND: about 150 µl, avoiding the formation of a convex meniscus.

- Cover the first 7 tests (PEN to URE) with mineral oil (underlined tests).

NOTE 1: The quality of the filling is very important: tubes which are insufficiently or excessively full may cause false positive or false negative results.

NOTE 2: Discard any strips which produce spontaneous reactions after inoculation and repeat the test on a new strip.

- Close the incubation box.
- Incubate for 2 to 2 ¼ hrs. at 36°C ± 2°C **in aerobic conditions**.

READING AND INTERPRETATION

Reading the Strip

After the incubation period, read the reactions by referring to the Reading Table in this package insert:

- Read the spontaneous reactions and record them as + or – on the result sheet.

Warning: The last 3 microtubes are bi-functional and enable the performance of 2 reactions in the same tube:

- 8. LIP (spontaneous reaction) / ProA (reaction after addition of reagent)
- 9. PAL (spontaneous reaction) / GGT (reaction after addition of reagent)
- 10. ßGAL (spontaneous reaction) / IND (reaction after addition of reagent).

The results of reactions LIP, PAL and ßGAL should be recorded before the addition of the reagent.

- Add 1 drop of ZYM B reagent to microtubes 8 and 9: LIP/ProA and PAL/GGT.
- Add 1 drop of JAMES reagent to microtube 10: ßGAL/IND.
- **Wait 3 minutes** then read the reactions by referring to the Reading Table in this package insert and record them on the result sheet.

- If the LIP reaction is positive (blue pigment), interpret the ProA reaction as **negative**, whether the ZYM B reagent has been added or not.
- If, after a 2-hour incubation period, several reactions (fermentation, penicillinase) are doubtful, re-incubate the strip for a further 2 hours and read the reactions again (the enzymatic tests should not be re-read in this case).

Interpretation

Identification is obtained with the **numerical profile**.

- Determination of the numerical profile:

On the result sheet, the tests are separated into groups of three and a value 1, 2 or 4 is assigned to each. By adding together the values corresponding to positive reactions within each group, a 4-digit numerical profile is obtained.

Warning: do not code the first test (penicillinase).

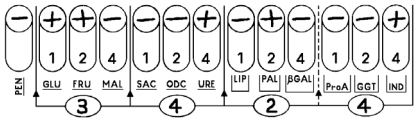
The first group consists of the tests GLU - FRU - MAL.

- Identification:

This is performed using the database (V3.0)

* with the numerical profile:
  - Look up the profile in the list in this package insert; this list is not exhaustive, so if the profile is missing, please consult one of the software programs indicated below or the bioMérieux Technical Assistance service.
* with the **api*web*™** identification software, ATB™ instrument or ***mini API*®**:
  - Enter the 4-digit numerical profile manually via the keyboard.

If there is low discrimination between several species, supplementary tests are indicated (Tables 1 and 2) to separate them. The results of these tests are taken from literature.



3 424 *Haemophilus influenzae*

- The biotyping of *H. influenzae* and *H. parainfluenzae* is performed using Table 1.

- Penicillinase test:

- A positive reaction (yellow, yellow-green or yellow-blue coloration) indicates the presence of a penicillinase. The presence of this enzyme prohibits the use of penicillins (Penicillin G, amino-, carboxy- and ureido-penicillins). A susceptibility test is required for the other ß-lactams.
- A negative reaction (blue coloration) indicates the absence of penicillinase.

QUALITY CONTROL

The media, strips and reagents are systematically controlled at various stages of their manufacture.

Streamlined quality control may be used to confirm acceptable performance of the API® NH system after shipping-storage. This methodology may be performed by following the instructions above for testing and meeting the criteria stated in CLSI® M50-A Quality Control for Commercial Microbial Identification Systems.

Testing may be conducted using ***Neisseria gonorrhoeae* ATCC® 31426™** to evaluate the performance of the PEN test. Testing performed by bioMérieux has shown that the PEN test is the most labile on the API NH strip. When testing the strip, *Neisseria gonorrhoeae* ATCC® 31426™ can be used to detect degradation.

For those users who are required to perform **comprehensive quality control** testing with the strip, the following three strains should be tested to demonstrate positive and negative reactivity for most of the API NH tests.

1. *Neisseria gonorrhoeae* ATCC® 31426™
2. *Haemophilus influenzae* ATCC® 10211™
3. *Haemophilus paraphrophilus* ATCC® 49917™

ATCC: American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209, USA.

	PEN	GLU	FRU	MAL	SAC	ODC	URE	LIP	PAL	ßGAL	ProA	GGT	IND
1.	+	+	–	–	–	–	–	–	–	–	+	–	–
2.	–	+	V	–	–	+	+	–	+	–	–	–	+
3.	–	+	+	+	+	–	–	–	+	+	–	+	–

Profiles obtained after culture of the strains on Chocolate agar + PolyViteX ™, after 2 or 4 hours of incubation (see § Reading the strip).

It is the responsibility of the user to perform Quality Control in accordance with any local applicable regulations.

LIMITATIONS OF THE METHOD

- The API® NH system is intended uniquely for the identification of those species included in the database (see Identification Table at the end of this package insert), i.e., those belonging to the genera *Neisseria* and *Haemophilus* (and related genera), and to the species *Moraxella catarrhalis* (*Branhamella catarrhalis*). It cannot be used to identify any other microorganisms or to exclude their presence.
- Certain species of the genera *Moraxella*, *Oligella,* etc. may be wrongly identified as *Neisseria meningitidis* and *Neisseria gonorrhoeae* since their biochemical profile on the API NH strip is very similar. *Neisseria meningitidis* profiles need to be confirmed by serological testing.
- If the result of the ProA test is negative when *Neisseria gonorrhoeae* is identified, this identification must be confirmed using an alternative method.
- For *Moraxella catarrhalis* (*Branhamella catarrhalis)*: *Moraxella* spp possible.
- For *Haemophilus aphrophilus/paraphrophilus: Haemophilus actinomycetemcomitans* possible - check catalase.
- Only pure cultures of a single organism should be used.

RANGE OF EXPECTED RESULTS

Consult the Identification Table at the end of this package insert for the range of expected results for the various biochemical reactions.

PERFORMANCE

- *Neisseria*

227 collection strains and strains of various origins belonging to species included in the database were tested:

- 99.1% of the strains were correctly identified (with or without supplementary tests).
- 0 % of the strains were not identified.
- 0.9% of the strains were misidentified.

- Haemophilus and related genera – Moraxella catarrhalis

402 collection strains and strains of various origins belonging to species included in the database were tested:

- 97.5% of the strains were correctly identified (with or without supplementary tests).
- 0.5% of the strains were not identified.
- 2 % of the strains were misidentified.

WASTE DISPOSAL

Dispose of unused ZYM B reagent following procedures for hazardous chemical waste.

Unused ampules of API® NaCl 0,85% Medium and JAMES reagent may be considered as non hazardous waste and disposed of accordingly.

Dispose of all used or unused reagents (other than the ZYM B and JAMES reagents and the ampules of API NaCl 0,85% Medium) 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 type and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

Limited Warranty

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

Except as expressly set forth above, bioMerieux hereby disclaims all warranties, including any implied warranties of merchantability and fitness for a particular purpose or use, and disclaims all liability, whether direct, indirect or consequential, for any use of the reagent, software, instrument and disposables (the “System”) other than as set forth in the IFU.

READING TABLE

TESTS	ACTIVE INGREDIENTS	QTY (mg/cup.)	REACTIONS/ENZYMES	RESULTS	
				NEGATIVE	POSITIVE
1) PEN	potassium benzylpenicillin	1.36	PENicillinase	blue (penicillinase absent)	yellow yellow-green yellow-blue (penicillinase present)
2) GLU	D-glucose	0.5	acidification (GLUcose)	red red-orange	yellow orange
3) FRU	D-fructose	0.1	acidification (FRUctose)		
4) MAL	D-maltose	0.1	acidification (MALtose)		
5) SAC	D-saccharose (sucrose)	0.5	acidification (SACcharose)		
6) ODC	L-ornithine	0.552	Ornithine DeCarboxylase	yellow-green grey-green	blue
7) URE	urea	0.41	UREase	yellow	pink-violet
8a) | LIP |	5-bromo-3-indoxyl-caprate	0.033	LIPase	colorless pale grey	blue (+ precipitate)
9a) | PAL |	4-nitrophenyl-phosphate 2CHA	0.038	ALkaline Phosphatase	colorless pale yellow	yellow
10a) | ßGAL |	4-nitrophenyl-ßD-galactopyranoside	0.04	ß GALactosidase	colorless	yellow
8b) | ProA |	proline-4-methoxy-ß-naphthylamide	0.056	Proline Arylamidase if LIP is +, ProA is always –	ZYM B / 3 min yellow pale orange (brown if LIP +)	orange
9b) | GGT |	γ-glutamyl-4-methoxy-ß-naphthylamide	0.049	Gamma Glutamyl Transferase	ZYM B / 3 min yellow pale orange (yellow-orange if PAL +)	orange
10b) | IND |	L-tryptophane	0.036	INDole	JAMES / 3 min colorless	pink

- The quantities indicated may be adjusted depending on the titer of the raw materials used.
- Certain cupules contain products of animal origin, notably peptones.

REVISION HISTORY

Change type categories:

N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user

Note: *Minor typographical, grammar, and formatting changes are not included in the revision history.*

Release date	Part Number	Change Type	Change Summary
2016/03	07487O	Technical	Composition Content of the kit Warning and precautions Storage conditions Use of the reagents
2016/12	07487P	Correction	Use of the reagents / Warnings and Precautions
		Administrative	Limited warranty

BIOMÉRIEUX

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

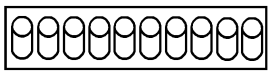
673 620 399 RCS LYON
Tél. 33 (0)4 78 87 20 00
Fax 33 (0)4 78 87 20 90
www.biomerieux.com

CE

METHODOLOGIE / PROCEDURE / METHODIK / TECNICA / PROCEDIMENTO / ΔΙΑΔΙΚΑΣΙΑ / METOD / METODYKA

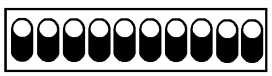
Chocolat PolyViteX™ / Chocolate PolyViteX

API® NaCl 0.85 % Medium



API NH

2:00 - 2:15 **36°C ± 2°C**



API NH

+ - + - + -

4 McF

PEN → URE

LIP ProA → ßGAL IND

PEN → URE

ProA] : **ZYM B**
GGT]
IND : **JAMES**

LISTE DES PROFILS NUMÉRIQUES / LIST OF NUMERICAL PROFILES / LISTE DER NUMERISCHEN PROFILE / LISTA DE PERFILES NUMÉRICOS / LISTA DEI PROFILI NUMERICI / LISTA DE PERFIS NUMÉRICOS / ΚΑΤΑΛΟΓΟΣ ΑΡΙΘΜΗΤΙΚΩΝ ΠΡΟΦΙΛ / LISTA ÖVER NUMERISKA PROFILER / LISTE OVER NUMERISKE PROFILER / LISTA PROFILI NUMERYCZNYCH

0 001	*Neisseria cinerea/Neisseria gonorrhoeae*	(2)
0 002	*Neisseria meningitidis**	
0 010	*Moraxella (Branhamella) catarrhalis***	
1 000	*Neisseria gonorrhoeae*	
1 001	*Neisseria gonorrhoeae*	
1 002	*Neisseria meningitidis**	
1 003	*Neisseria meningitidis**	
1 010	*Moraxella (Branhamella) catarrhalis***	
1 020	*Haemophilus influenzae*	(1)
1 024	*Haemophilus influenzae*	(1)
1 103	*Neisseria spp*	(2)
1 224	*Haemophilus influenzae*	(1)
1 420	*Haemophilus influenzae*	(1)
1 424	*Haemophilus influenzae*	(1)
1 426	*Haemophilus influenzae*	(1)
1 620	*Haemophilus influenzae*	(1)
1 624	*Haemophilus influenzae*	(1)
1 626	*Haemophilus influenzae*	(1)
1 720	*Haemophilus parainfluenzae/influenzae*	
3 001	*Neisseria spp*	(2)
3 003	*Neisseria spp*	(2)
3 024	*Haemophilus influenzae*	(1)
3 026	*Haemophilus influenzae*	(1)
3 101	*Neisseria spp*	(2)
3 103	*Neisseria spp*	(2)
3 120	*Haemophilus paragallinarum*	
3 122	*Haemophilus paragallinarum/aphrophilus/ paraphrophilus/ parainfluenzae***	
3 160	*Haemophilus aphrophilus/paraphrophilus/parainfluenzae***	(1)
3 162	*Haemophilus aphrophilus/paraphrophilus***	(1)
3 200	*Histophilus somni*	
3 204	*Histophilus somni*	
3 220	*Haemophilus influenzae*	(1)
3 224	*Haemophilus influenzae*	(1)
3 320	*Haemophilus parainfluenzae*	(1)
3 324	*Haemophilus parainfluenzae/influenzae*	
3 360	*Haemophilus parainfluenzae*	(1)
3 420	*Haemophilus influenzae*	(1)
3 422	*Haemophilus influenzae*	(1)
3 424	*Haemophilus influenzae*	(1)
3 426	*Haemophilus influenzae*	(1)
3 520	*Haemophilus parainfluenzae/influenzae*	
3 524	*Haemophilus influenzae/ parainfluenzae*	
3 620	*Haemophilus influenzae*	(1)
3 622	*Haemophilus influenzae*	(1)
3 624	*Haemophilus influenzae*	(1)
3 626	*Haemophilus influenzae*	(1)
3 720	*Haemophilus parainfluenzae/influenzae*	
3 724	*Haemophilus influenzae/parainfluenzae*	
3 760	*Haemophilus parainfluenzae*	(1)
4 002	*Neisseria meningitidis**	
4 003	*Neisseria meningitidis**	
5 001	*Neisseria polysaccharea/Neisseria spp*	(2)
5 002	*Neisseria meningitidis**	
5 003	*Neisseria meningitidis**	
5 041	*Neisseria lactamica*	
5 060	*Haemophilus aphrophilus/paraphrophilus***	(1)
5 100	*Neisseria polysaccharea/Neisseria spp*	(2)
5 101	*Neisseria polysaccharea/Neisseria spp*	(2)
5 103	*Neisseria spp*	(2)
5 120	*Haemophilus parainfluenzae/aphrophilus paraphrophilus***	(1)
5 122	*Haemophilus aphrophilus/paraphrophilus parainfluenzae***	(1)
5 160	*Haemophilus aphrophilus/paraphrophilus parainfluenzae***	(1)
5 162	*Haemophilus aphrophilus/paraphrophilus***	(1)
5 320	*Haemophilus parainfluenzae*	(1)
5 324	*Haemophilus parainfluenzae*	(1)
5 360	*Haemophilus parainfluenzae*	(1)
5 420	*Haemophilus influenzae/parainfluenzae*	
5 424	*Haemophilus influenzae*	(1)
5 520	*Haemophilus parainfluenzae*	(1)
5 620	*Haemophilus influenzae/parainfluenzae*	
5 624	*Haemophilus influenzae*	(1)
5 720	*Haemophilus parainfluenzae*	(1)
5 724	*Haemophilus parainfluenzae*	(1)
5 760	*Haemophilus parainfluenzae*	(1)
7 000	*Neisseria spp*	(2)
7 001	*Neisseria spp*	(2)
7 003	*Neisseria spp*	(2)
7 020	*Haemophilus aphrophilus/paraphrophilus/ parainfluenzae/influenzae***	
7 022	*Haemophilus aphrophilus/paraphrophilus/ parainfluenzae/influenzae***	
7 024	*Haemophilus influenzae/parainfluenzae*	
7 060	*Haemophilus aphrophilus/paraphrophilus***	(1)
7 062	*Haemophilus aphrophilus/paraphrophilus***	(1)
7 100	*Neisseria spp/Haemophilus parainfluenzae*	(2)
7 101	*Neisseria spp*	(2)
7 103	*Neisseria spp*	(2)
7 120	*Haemophilus aphrophilus/paraphrophilus/parainfluenzae***	(1)
7 122	*Haemophilus aphrophilus/paraphrophilus/parainfluenzae***	(1)
7 124	*Haemophilus parainfluenzae*	(1)
7 160	*Haemophilus aphrophilus/paraphrophilus***	(1)
7 162	*Haemophilus aphrophilus/paraphrophilus***	(1)
7 164	*Haemophilus parainfluenzae*	(1)
7 220	*Haemophilus parainfluenzae/influenzae*	
7 224	*Haemophilus influenzae/parainfluenzae*	
7 260	*Haemophilus parainfluenzae*	(1)
7 300	*Haemophilus parainfluenzae*	(1)
7 320	*Haemophilus parainfluenzae*	(1)
7 322	*Haemophilus parainfluenzae*	(1)
7 324	*Haemophilus parainfluenzae*	(1)
7 326	*Haemophilus parainfluenzae*	(1)
7 340	*Haemophilus parainfluenzae*	(1)
7 360	*Haemophilus parainfluenzae*	(1)
7 362	*Haemophilus parainfluenzae*	(1)
7 364	*Haemophilus parainfluenzae*	(1)
7 420	*Haemophilus influenzae/parainfluenzae*	
7 424	*Haemophilus influenzae*	(1)
7 426	*Haemophilus influenzae*	(1)
7 500	*Haemophilus parainfluenzae*	(1)
7 520	*Haemophilus parainfluenzae*	(1)
7 522	*Haemophilus parainfluenzae*	(1)
7 524	*Haemophilus parainfluenzae/influenzae*	
7 560	*Actinobacillus pleuropneumoniae/H. parainfluenzae*	(1)
7 564	*Haemophilus parainfluenzae*	(1)
7 620	*Haemophilus influenzae/parainfluenzae*	
7 624	*Haemophilus influenzae/parainfluenzae*	
7 626	*Haemophilus influenzae*	(1)
7 660	*Haemophilus parainfluenzae*	(1)
7 700	*Haemophilus parainfluenzae*	(1)
7 720	*Haemophilus parainfluenzae*	(1)
7 722	*Haemophilus parainfluenzae*	(1)
7 724	*Haemophilus parainfluenzae*	(1)
7 726	*Haemophilus parainfluenzae*	(1)
7 740	*Haemophilus parainfluenzae*	(1)
7 760	*Haemophilus parainfluenzae*	(1)
7 762	*Haemophilus parainfluenzae*	(1)
7 764	*Haemophilus parainfluenzae*	(1)

* A confirmer par tests sérologiques / Confirm by serological testing

** Voir § Limites du test / See § Limitations of the method

(1) voir Tableau 1 / see Table 1

(2) voir Tableau 2 / see Table 2

TABLEAU 1 / TABLE 1 / TABELLE 1 / TABLA 1 / TABELLA 1 / QUADRO 1 / ΠΙΝΑΚΑΣ 1 / TABELL 1 / TABEL 1 / TABELA 1
(Biblio. / Lit. 3 + 2 + 5 + 7)

	IND	URE	Fact. V	ODC	Fact. X	CAT	OX
Haemophilus aphrophilus	—	—	—	—	—	—	—
Haemophilus paraphrophilus	—	—	+	—	—	—	+
Haemophilus actinomycetemcomitans	—	—	—	—	NT	+	NT
Haemophilus influenzae I	+	+	+	+	+	+	+
Haemophilus influenzae II	+	+	+	—	+	+	+
Haemophilus influenzae III	—	+	+	—	+	+	+
Haemophilus influenzae IV	—	+	+	+	+	+	+
Haemophilus influenzae V	+	—	+	+	+	+	+
Haemophilus influenzae VI	—	—	+	+	+	+	+
Haemophilus influenzae VII	+	—	+	—	+	+	+
Haemophilus influenzae VIII	—	—	+	—	+	+	+
Haemophilus parainfluenzae I	—	—	+	+	—	NT	+
Haemophilus parainfluenzae II	—	+	+	+	—	NT	+
Haemophilus parainfluenzae III	—	+	+	—	—	NT	+
Haemophilus parainfluenzae IV	+	+	+	+	—	NT	+
Haemophilus parainfluenzae VI	+	—	+	+	—	NT	+
Haemophilus parainfluenzae VII	+	+	+	—	—	NT	+
Haemophilus parainfluenzae VIII	+	—	+	—	—	NT	+
Actinobacillus pleuropneumoniae	—	+	NT	—	—	— / +	+ / —
Haemophilus paragallinarum	—	—	NT	—	—	—	—

TABLEAU 2 / TABLE 2 / TABELLE 2 / TABLA 2 / TABELLA 2 / QUADRO 2 / ΠΙΝΑΚΑΣ 2 / TABELL 2 / TABEL 2 / TABELA 2
(Biblio. / Lit. 5)

	NO_3 (red.)	$NO_2 \rightarrow N_2$	agar 35°C	JAUNE / YELLOW / GELB / AMARELO / KITPINO / GUL
Neisseria polysaccharea	—	V	+	V
Neisseria sicca	—	+	+	—
Neisseria subflava	—	+	+	+
Neisseria mucosa	+	+	+	— / +
Haemophilus parainfluenzae	+	+	NT	—
Haemophilus influenzae	+	—	NT	—
Neisseria cinerea	—	+	+	—
Neisseria gonorrhoeae	—	—	—	—

NT : Non testé / Not tested / Nicht getestet / No testado / Non testato / Não testado / Δεν ελέγχθηκε / Ej testad / Ikke testet / Nie testowano

TABLEAU D'IDENTIFICATION / IDENTIFICATION TABLE / PROZENTTABELLE / TABLA DE IDENTIFICACION / TABELLA DI IDENTIFICAZIONE / QUADRO DE IDENTIFICAÇÃO / ΠΙΝΑΚΑΣ ΤΑΥΤΟΠΟΙΗΣΗΣ / IDENTIFIERINGSTABELL / IDENTIFIKATIONSTABEL / TABELA IDENTYFIKACYJNA

% de réactions positives après 2 H - 2 H 15 / 4 H à 36°C ± 2°C /
% of positive reactions after 2 - 2 ¼ hrs. / 4 hrs. at 36°C ± 2°C /
% der positiven Reaktionen nach 2 Std. - 2 Std. 15 / 4 Std. bei 36°C ± 2°C /
% de las reacciones positivas después de 2 H - 2 H 15 / 4 H a 36°C ± 2°C /
% di reazioni positive dopo 2 ore - 2 ore 15 / 4 ore a 36°C ± 2°C /
% das reacções positivas após 2 H - 2 H 15 / 4 H a 36º C ± 2º C /
% θετικών αντιδράσεων μετά από 2 - 2 ¼ ώρες / 4 ώρες στους 36°C ± 2°C /
% positiva reaktioner efter 2 - 2 ¼ h. / 4 h. vid 36°C ± 2°C /
% af positive reaktioner efter 2 - 2 ¼ / 4 timer ved 36°C ± 2°C /
% pozytywnych reakcji po 2 - 2 ¼ godzinach / 4 godzinach w 36°C ± 2°C

API NH V3.0	GLU	FRU	MAL	SAC	ODC	URE	LIP	PAL	ßGAL	PRO	GGT	IND
Actinobacillus pleuropneumoniae	**100**	**100**	**100**	**100**	0	**100**	0	**100**	**100**	0	0	0
Haemophilus aphrophilus/paraphrophilus **	**100**	**96**	**99**	**96**	0	0	0	**100**	**88**	0	**29**	0
Haemophilus influenzae	**100**	**89**	12	1	**40**	**92**	0	**100**	0	0	5	**74**
Haemophilus paragallinarum	**100**	**100**	**0**	**100**	0	0	0	**100**	0	0	1	0
Haemophilus parainfluenzae	**100**	**94**	**94**	**97**	**73**	**55**	0	**97**	**30**	0	5	11
Histophilus somni	**100**	**100**	0	0	**100**	0	0	0	0	0	0	**50**
Moraxella (Branhamella) catarrhalis **	1	0	0	0	0	0	**100**	0	0	0	0	0
Neisseria cinerea	0	0	0	0	0	0	0	0	0	**95**	0	0
Neisseria gonorrhoeae	**97**	0	0	0	0	0	0	0	0	**99**	0	0
Neisseria lactamica	**100**	0	**100**	0	0	0	0	0	**100**	**100**	0	0
Neisseria meningitidis	**97**	0	**90**	0	0	0	0	0	0	**44**	**100**	0
Neisseria polysaccharea	**100**	0	**100**	**75**	0	0	0	0	0	**99**	0	0
Neisseria spp *	**100**	**80**	**86**	**65**	0	0	0	0	0	**99**	7	0

* *Neisseria* spp = *N. sicca, N. mucosa, N. subflava*

** Voir § Limites du test / See § Limitations of the method / Siehe § Limitierungen / Ver § Límites del método / Vedere § Limiti del metodo / Consultar § Limites do teste / Βλέπε § Περιορισμοί Μεθόδου / Se avsnittet “Metodens begränsningar“ / Se § Metodens begrænsninger / Patrz § Ograniczenia testu

BIBLIOGRAPHIE / LITERATURE REFERENCES / LITERATUR / BIBLIOGRAFIA / ΑΝΑΦΟΡΕΣ ΑΡΘΡΟΓΡΑΦΙΩΝ / REFERENSLITTERATUR / LITTERATURHENVISNINGER / PIŚMIENNICTWO

1. ANGEN O., AHRENS P., KUHNERT P., CHRISTENSEN H. and MUTTERS R.
   Proposal of *Histophilus somni* gen. nov., sp. nov. for the three species incertae sedis "*Haemophilus somnus*", "*Haemophilus agni*" and "*Histophilus ovis*".
   (2003) Int. J. Syst. Evol.Microbiol., 53, 1449-1456.
2. BARBE G. BABOLAT M., BOEUFGRAS J.M., MONGET D., FRENEY J.
   Evaluation of API NH, a new 2-hour system for identification of *Neisseria* and *Haemophilus* species and *Moraxella catarrhalis* in a routine clinical laboratory.
   (1994) J. Clin. Microbiol., 32, 1, 187-189.
3. BIBERSTEIN E.L. and WHITE D.C. :
   A proposal for the establishment of two new *Haemophilus* species.
   (1969) J. Med. Microbiol., 2, 75-78.
4. BOVRE K.
   Proposal to divide the genus *Moraxella* Lwoff 1939 emend. Henriksen and Bovre 1968 into two subgenera – subgenerus *Moraxella* (Lwoff 1939) Bovre 1979 and subgenerus *Branhamella* (Catlin 1970) Bovre 1979.
   (1979) Int. J. Syst. Bacteriol., 29, 403-406.
5. DOERN G.V., CHAPIN K.C.
   Determination of Biotypes of *Haemophilus influenzae* and *Haemophilus parainfluenzae*.
   A comparison of Methods and a Description of a New Biotype (VIII) of *H. parainfluenzae.*
   (1987) Diagn. Microbiol. Infect. Dis., 7, 269-272.
6. KNAPP J.S.
   Historical Perspectives and Identification of *Neisseria* and Related Species.
   (1988) Clin. Microbiol. Reviews, 1, 415-431.
7. KRIEG N.R., HOLT J.G.
   Bergey's Manual of Systematic Bacteriology.
   8th edition, volume 1.
   (1984) Williams & Wilkins Co., Baltimore, MD.
8. McCARTHY L.R.
   Identification and Taxonomy of the Genus *Haemophilus.*
   (1983) Clin. Microbiol. Newsl., 5, 1-3.
9. MURRAY P.R., BARON E.J., JORGENSEN J.H., PFALLER M.A., YOLKEN R.H.
   Manual of Clinical Microbiology.
   8th Edition.
   (2003) American Society for Microbiology, Washington, D.C.
10. POHL S., BERTSCHINGER H.U., FREDERIKSEN W. and MANNHEIM W.
    Transfer of *Haemophilus pleuropneumoniae* and the *Pasteurella haemolytica*-like organism causing porcine necrotic pleuropneumonia to the genus *Actinobacillus* (*Actinobacillus pleuropneumoniae* comb. nov.) on the basis of phenotypic and deoxyribonucleic acid relatedness.
    (1983) Int. J. Syst. Bacteriol., 33, 510-514.
11. POTTS T.V., ZAMBON J.J. and GENCO R.J.
    Reassignment of *Actinobacillus actinomycetemcomitans* to the genus *Haemophilus* as *Haemophilus actinomycetemcomitans* comb. nov.
    (1985) Int. J. Syst. Bacteriol., 35, 337-341.
12. RIOU J.Y., GUIBOURDENCHE M.
    Diagnostic bactériologique des espèces des genres *Neisseria* et *Branhamella.*
    (1977) Ann. Biol. Clin., 35, 73-87.
13. Clinical and Laboratory Standards Institute, M50-A, Quality Control for Commercial Microbial Identification Systems; Approved Guideline, Vol 23 n° 23.

TABLE DES SYMBOLES / INDEX OF SYMBOLS / SYMBOLE / CUADRO DE SIMBOLOS / TABELLA DEI SIMBOLI / QUADRO DOS SÍMBOLOS / ΠΙΝΑΚΑΣ ΣΥΜΒΟΛΩΝ / SYMBOLER / SYMBOLFORTEGNELSE / TABELA SYMBOLI

Symbole / Symbol / Símbolo / Simbolo / Σύμβολο	Signification / Meaning / Bedeutung / Significado / Significato / Επεξήγηση / Betydelse / Betydning / Znaczenie
	Référence du catalogue / Catalogue number (GB) / Catalog number (US) Bestellnummer / Número de catálogo / Numero di catalogo / Referência de catálogo / Αριθμός καταλόγου / Katalognummer / Katalognummer / Numer katalogowy
	Dispositif médical de diagnostic *in vitro* / *In Vitro* Diagnostic Medical Device *In Vitro* Diagnostikum / Producto sanitario para diagnóstico *in vitro* Dispositivo medico-diagnostico *in vitro* / Dispositivo médico para diagnóstico *in vitro* / *In Vitro* Διαγνωστικό Ιατροτεχνολογικό προϊόν / Medicintekniska produkter för *in vitro* diagnostik / Medicinsk udstyr til *in vitro*-diagnostik / Wyrób do diagnostyki *In Vitro*
	Fabricant / Manufacturer / Hersteller / Fabricante / Fabbricante Κατασκευαστής / Tillverkare / Producent
	Limites de température / Temperature limit / Temperaturbegrenzung Límite de temperatura / Limiti di temperatura / Limites de temperatura Περιορισμοί θερμοκρασίας / Temperaturbegränsning Temperaturbegrænsning / Przestrzegać zakresu temperatury
	Utiliser jusque / Use by date / Verwendbar bis / Fecha de caducidad / Utilizzare entro / Prazo de validade / Ημερομηνία λήξης / Använd före / Holdbar til / Użyć przed
	Code du lot / Batch code / Chargenbezeichnung / Código de lote / Codice del lotto / Código do lote / Αριθμός Παρτίδας / Lot nummer / Lotnummer / Kod partii
	Consulter les instructions d'utilisation / Consult Instructions for Use Gebrauchsanweisung beachten / Consulte las instrucciones de uso Consultare le istruzioni per l'uso / Consulte as instruções de utilização Συμβουλευτείτε τις οδηγίες χρήσης / Se handhavandebeskrivningen Se brugsanvisning / Sprawdź w instrukcji obsługi
	Conserver à l'abri de la lumière / Protect from light / Lichtgeschützt lagern Conservar protegido de la luz / Conservare al riparo della luce Conservar ao abrigo da luz / Προστατέψτε από το φως / Skyddas mot ljus Beskyttes mod lys / Chronić przed światłem
	Contenu suffisant pour "n" tests / Contains sufficient for <n> tests Inhalt ausreichend für <n> Prüfungen / Contenido suficiente para <n> ensayos Contenuto sufficiente per "n" saggi / Conteúdo suficiente para “n” ensaios Περιεχόμενο επαρκές για «ν» εξετάσεις / Räcker till "n" antal tester Indeholder tilstrækkeligt til "n" test / Wystarczy na wykonanie <n> testów
	Date de fabrication / Date of manufacture / Herstellungsdatum / Fecha de fabricación / Data di fabbricazione / Data de fabrico / Ημερομηνία Παραγωγής / Tillverkningsdatum / Produktionsdato / Data produkcji

BIOMÉRIEUX

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