api® 20 Strep

IVD

Identification system for *Streptococcaceae* and related organisms

SUMMARY AND EXPLANATION

API 20 Strep is a standardized system combining 20 biochemical tests that offer widespread capabilities. It enables group or species identification of most streptococci and enterococci, and those most common related organisms. 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 this package insert.

PRINCIPLE

The API 20 Strep strip consists of 20 microtubes containing dehydrated substrates for the demonstration of enzymatic activity or the fermentation of sugars.
The enzymatic tests are inoculated with a dense suspension of organisms, made from a pure culture, which is used to reconstitute the enzymatic substrates. During incubation, metabolism produces color changes that are either spontaneous or revealed by the addition of reagents.
The fermentation tests are inoculated with an enriched medium which rehydrates the sugar substrates. Fermentation of carbohydrates is detected by a shift in the pH indicator.
The reactions are read according to the Reading Table and the identification is obtained by referring to the Analytical Profile Index or using the identification software.

CONTENT OF THE KIT (Kit for 25 tests)

- 25 API 20 Strep strips
- 25 incubation boxes
- 25 ampules of API GP Medium
- 25 result sheets
- 1 package insert

COMPOSITION

Strip

The composition of the API 20 Strep strip is given in the Reading Table of this package insert.

Medium

API GP Medium 2 ml	L-cystine	0.5 g
	Tryptone (bovine/porcine origin)	20 g
	Sodium chloride	5 g
	Sodium sulfite	0.5 g
	Phenol red	0.17 g
	Demineralized water	to make 1000 ml
	pH : 7.4 - 7.6	

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

REAGENTS AND MATERIAL REQUIRED BUT NOT PROVIDED

Reagents / Instrumentation

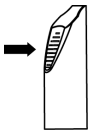
- API® Suspension Medium, 2 ml (Ref. 70 700)
- Reagents : NIN (Ref. 70 491)
  VP 1 + VP 2 (Ref. 70 422)
  ZYM A (Ref. 70 494)
  ZYM B (Ref. 70 493)
- Mineral oil (Ref. 70 100)
- McFarland Standard (Ref. 70 900) point 4 on the scale or DENSIMAT (Ref. 99 234)
- API 20 Strep Analytical Profile Index (Ref. 20 690)
  or **api*web*** ™ identification software (Ref. 40 011) (consult bioMérieux)
- Columbia blood agar plates (Ref. 43 041)
- Schaedler broth (optional)

Material

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

WARNINGS AND PRECAUTIONS

- **For *in vitro* diagnostic use and microbiological control.**
- **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 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 past 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.
- It is recommended to perform a quality control test when a new ampule of ZYM B reagent is opened.
- 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.
  - 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

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

SPECIMENS (COLLECTION AND PREPARATION)

API 20 Strep 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

Once the microorganism to be identified has been isolated and verified to be a member of the family *Streptococcaceae* (Gram, catalase test) :

- Note the type of hemolysis on the result sheet (21st test).
- Pick a well-isolated colony (Note 1) and suspend it in 0.3 ml of sterile water. Homogenize well.
- Flood a Columbia sheep blood agar plate (Note 2) with this suspension (or aseptically swab the entire surface of the agar).
- Incubate the plate for 24 hours (± 2 hours) at 36°C ± 2°C in anaerobic conditions.

NOTE 1 : ß-hemolytic streptococci and enterococci produce sufficiently large colonies after 24 hours of incubation. For other streptococci, it is preferable to select a colony after 48 hours of incubation. For fastidious strains (producing minute colonies after 48 hours), the following procedure is recommended :

- Culture the colony in 1 ml of Schaedler broth at 36°C ± 2°C for 5 hours.
- Flood a Columbia sheep blood agar plate with the entire culture. Remove any excess liquid.
- Incubate the plate for 18-24 hours at 36°C ± 2°C in anaerobic conditions.

NOTE 2 : In the case of suspected pneumococci, it is advisable to prepare 2 agar plates in order to obtain sufficient growth.

Preparation of the strip

- Prepare an incubation box (tray and lid) and distribute about 5 ml of distilled water or demineralized water [or any water without additives or chemicals which may release gases (e.g. Cl_2, CO_2, etc.)] into the honeycombed wells of the tray to create a humid atmosphere.
- 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.

Preparation of the inoculum

- Open an ampule of API Suspension Medium (2 ml) as indicated in the paragraph "Warnings and Precautions" or use any tube containing 2 ml of distilled water without additives.
- Using a swab, harvest all the culture from the previously prepared subculture plate.
- Make a dense suspension with a **turbidity greater than 4 McFarland.** This suspension must be used immediately after preparation.

Inoculation of the strip

- In the first half of the strip (tests VP to ADH), distribute this suspension, 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) :
  - For the tests VP to LAP : distribute approximately 100 µl into each cupule.
  - For the ADH test : fill the tube only.
- In the second half of the strip (tests RIB to GLYG) :
  - Open an ampule of API GP Medium as indicated in the paragraph "Warnings and Precautions" and transfer the rest of the suspension into it (appr. 0.5 ml). Mix well.
  - Distribute this new suspension into the tubes only.
- Fill the cupule of the underlined tests (ADH to GLYG) with mineral oil to form a convex meniscus.
- Place the lid on the tray.
- Incubate at 36°C ± 2°C in aerobic conditions for 4 - 4 ½ hours to obtain a first reading and for 24 hours (± 2 hours) to obtain a second reading if required.

READING AND INTERPRETATION

Reading the strip

After 4 hours of incubation :

- Add the reagents :
  - VP test : 1 drop of each of VP 1 and VP 2.
  - HIP test : 2 drops of NIN.
  - PYRA, αGAL, ßGUR, ßGAL, PAL and LAP tests : 1 drop of each of ZYM A and ZYM B (*).
    (*) **It is recommended to control** each ampule of ZYM B before using for the first time.
    To do this, it is recommended to use **the strain ATCC® 700400** indicated in the Quality Control paragraph in order to eliminate any defective reagents.
- Wait 10 minutes, then read the reactions by referring to the Reading Table. If necessary, expose the strip to a strong light (10 seconds with a 1000 W lamp) to decolorize any excess reagents in tubes PYRA to LAP.

Reincubation is necessary in the following cases :

- low discrimination ;
- unacceptable or doubtful profile ;
- or if the following comment is given for the profile :

IDENTIFICATION NOT VALID
BEFORE 24 HOURS OF INCUBATION

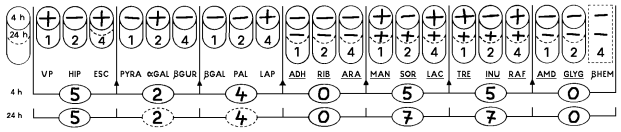
In this case, after 24 hours, reread the reactions ESC, ADH, and RIB to GLYG. **Do not reread the enzymatic reactions** (HIP, PYRA, αGAL, ßGUR, ßGAL, PAL, LAP) and VP. Record all the reactions on the result sheet.

Interpretation

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

- Determination of the numerical profile :
  On the result sheet, the tests are separated into groups of 3 and a value of 1, 2 or 4 is indicated for each. By adding together the values corresponding to positive reactions within each group, a 7-digit profile number is obtained.

- Identification :
  This is performed using the database (V 7.0)
  * with the Analytical Profile Index :
    - Look up the numerical profile in the list of profiles.
  * with the **api*web*** **TM** identification software :
    - Enter the 7-digit numerical profile manually via the keyboard.



5 240 550 / 5 240 770 *Streptococcus mutans*

NOTE : The hemolytic reaction constitutes the 21st test ; ß-hemolysis is considered as positive with a numerical value of 4. All other hemolytic reactions are considered as negative with a numerical value of 0. Nevertheless, this test may be of discriminant value for the identification of certain species.

QUALITY CONTROL

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

Streamlined quality control may be used to confirm acceptable performance of the API 20 Strep 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 ***Streptococcus equi* spp *zooepidemicus* ATCC® 700400** to evaluate the performance of the ARA test. Testing performed by bioMérieux has shown that the ARA test is the most labile on the API 20 Strep strip. When testing the strip, *Stretococcus equi* spp *zooepidemicus* ATCC 700400 can be used to detect degradation.

For those users who are required to perform **comprehensive quality control** testing with the strip, the following two strains should be tested to demonstrate positive and negative reactivity for most of the API 20 Strep tests.

1. *Streptococcus equi* spp *zooepidemicus* ATCC 700400 2. *Streptococcus uberis* ATCC 700407

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

	VP	HIP	ESC	PYRA	αGAL	ßGUR	ßGAL	PAL	LAP	ADH	RIB	ARA	MAN	SOR	LAC	TRE	INU	RAF	AMD	GLYG
1.	–	–	–	–	–	+	–	+	+	+	+	–	–	+	+	–	–	–	+	+
2.	+	+	+	V	V	+	–	–*	+	+	+	–	+	+	+	+	+	+	–	–

* This result may vary depending on the culture medium used.

- Inoculum adjusted to between 4.5 and 5.5 McF using DENSIMAT.
- Profiles obtained after : - 4 hours of incubation for tests VP to LAP
  - 24 hours of incubation for tests ADH to GLYG.
- Strains cultured on Columbia sheep blood agar.

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

LIMITATIONS OF THE METHOD

- The API 20 Strep system is intended uniquely for the identification of those species included in the database (see Identification Table at the end of this package insert). It cannot be used to identify any other microorganisms or to exclude their presence.
- Certain strains of *Streptococcus porcinus* may be identified as *Streptococcus agalactiae*.
- 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

- After 4 hours of incubation:
  2336 collection strains and strains of various origins belonging to species included in the database were tested :
  - 87.9 % of the strains were correctly identified (with or without supplementary tests).
  - 5.7 % of the strains were not identified.
  - 6.4 % of the strains were misidentified.
- After 24 hours of incubation:
  3782 collection strains and strains of various origins belonging to species included in the database were tested :
  - 93.4 % of the strains were correctly identified (with or without supplementary tests).
  - 3.2 % of the strains were not identified.
  - 3.4 % of the strains were misidentified.

WASTE DISPOSAL

Dispose of used or unused 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 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.

WARRANTY

bioMérieux disclaims all warranties, express or implied, including any implied warranties of MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE. bioMérieux shall not be liable for any incidental or consequential damages. IN NO EVENT SHALL BIOMERIEUX'S LIABLITY TO CUSTOMER UNDER ANY CLAIM EXCEED A REFUND OF THE AMOUNT PAID TO BIOMERIEUX FOR THE PRODUCT OR SERVICE WHICH IS THE SUBJECT OF THE CLAIM.

READING TABLE

TESTS	ACTIVE INGREDIENTS	QTY (mg/cup.)	REACTIONS/ENZYMES	RESULTS			
				NEGATIVE		POSITIVE	
VP	sodium pyruvate	1.9	acetoin production (Voges Proskauer)	VP 1 + VP 2 / wait 10 min (3) Colorless		Pink-Red	
HIP	hippuric acid	0.4	hydrolysis (HIPpuric acid)	NIN / wait 10 min Colorless/Pale blue Bluish-grey		Dark blue/Violet	
ESC	esculin ferric citrate	1.16 0.152	ß-glucosidase hydrolysis (ESCulin)	4 hrs. Colorless Pale yellow	24 hrs. Colorless Pale yellow Light grey	4 hrs. Black Grey	24 hrs. Black
PYRA	pyroglutamic acid-ß-naphthylamide	0.0256	PYRrolidonyl Arylamidase	ZYM A + ZYM B / 10 min (PYRA to LAP) (1) if necessary, decolorize with intense light Colorless or very pale orange		Orange	
αGAL	6-bromo-2-naphthyl-αD-galactopyranoside	0.0376	α-GALactosidase	Colorless		Violet	
ßGUR	naphthol ASBI-glucuronic acid	0.0537	ß-GlUcuRonidase	Colorless		Blue	
ßGAL	2-naphthyl-ßD-galactopyranoside	0.0306	ß-GALactosidase	Colorless or Very pale violet		Violet	
PAL	2-naphthyl phosphate	0.0244	ALkaline Phosphatase	Colorless or Very pale violet		Violet	
LAP	L-leucine-ß-naphthylamide	0.0256	Leucine AminoPeptidase	Colorless		Orange	
ADH	L-arginine	1.9	Arginine DiHydrolase	Yellow		Red	
				4 hrs.	24 hrs.	4 hrs.	24 hrs.
RIB	D-ribose	1.4	acidification (RIBose)	Red	Orange/ Red	Orange/ Yellow	Yellow
ARA	L-arabinose	1.4	acidification (ARAbinose)	Red	Orange/ Red	Orange/ Yellow	Yellow
MAN	D-mannitol	1.36	acidification (MANnitol)	Red	Orange/ Red	Orange/ Yellow	Yellow
SOR	D-sorbitol	1.36	acidification (SORbitol)	Red	Orange/ Red	Orange/ Yellow	Yellow
LAC	D-lactose (bovine origin)	1.4	acidification (LACtose)	Red	Orange/ Red	Orange/ Yellow	Yellow
TRE	D-trehalose	1.32	acidification (TREhalose)	Red	Orange/ Red	Orange/ Yellow	Yellow
INU	inulin	5.12	acidification (INUlin)	Red	Orange/ Red	Orange/ Yellow	Yellow
RAF	D-raffinose	3.12	acidification (RAFfinose)	Red	Orange/ Red	Orange/ Yellow	Yellow
AMD	starch (2)	2.56	acidification (AmiDon)	Red	Orange/ Red	Orange/ Yellow	Yellow
GLYG	glycogen	1.28	acidification (GLYcoGen)	Red or Orange		Bright yellow	

(1) During a second reading after 24 hours of incubation, a deposit may be noticed in the tubes where the ZYM A and ZYM B reagents have been added. This phenomenon is normal and should not be taken into consideration.
(2) The acidification of starch is frequently weaker than that of other sugars.
(3) A pale pink color obtained after 10 minutes should be considered negative.

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

BIOMÉRIEUX

bioMérieux SA
RCS LYON 673 620 399
69280 Marcy-l'Etoile / France
Tél. 33 (0)4 78 87 20 00
Fax 33 (0)4 78 87 20 90
www.biomerieux.com

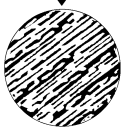
bioMérieux, Inc
Box 15969,
Durham, NC 27704-0969 / USA
Tél. (1) 919 620 20 00
Fax (1) 919 620 22 11
Imprimé en France

CE

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

Gélose au sang / Blood agar / Blutagar / Agar con sangre / Agar al sangue / Gelose de sangue / Αιματούχο άγαρ / Blodagar / Agar krwawy

- Cocci / Kokken / Cocos / Cocchi / Κόκκοι / Kocker / Kokker / Ziarniaki
- Gram +
- Catalase / Katalase / Catalasa / Catalasi / Καταλάση / Katalas / Katalase / Katalaza –

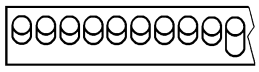


Gélose Columbia au sang / Columbia blood agar / Columbia Blutagar / Agar Columbia con sangre / Agar Columbia al sangue / Gelose Columbia de sangue / Αιματούχο άγαρ Columbia / Columbia blodagar / Agar Columbia z krwią

24:00 ± 2:00 $\not{O_2}$ **36°C ± 2°C**

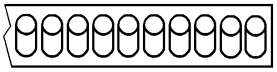
> 4 McF

API Suspension Medium 2 ml



~ 500 µl

API GP Medium



VP → ADH

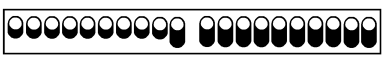
ADH

RIB → GLYG

RIB → GLYG

4:00 – 4:30 **36°C ± 2°C**

24:00 ± 2:00 **36°C ± 2°C**



API 20 Strep

VP : **VP 1 + VP 2**
HIP : **NIN**
PYRA → LAP : **ZYM A + ZYM B**

+ - + - + -

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 4/24 h à 36°C ± 2°C / % of reactions positive after 4/24 hrs. at 36°C ± 2°C /
% der positiven Reaktionen nach 4/24 h bei 36°C ± 2°C / % de las reacciones positivas después de 4/24 H a 36°C ± 2°C /
% di reazioni positive dopo 4/24 ore a 36°C ± 2°C / % das reacções positivas após 4/24 H a 36°C ± 2°C /
% θετικών αντιδράσεων μετά από 4/24 ώρες στους 36°C ± 2°C / % positiva reaktioner efter 4/24 timmar vid 36°C ± 2°C /
% positive reaktioner efter 4/24 timer ved 36°C ± 2°C/ % pozytywnych reakcji po 4/24 godzinach w 36°C ± 2°C

API 20 STREP V7.0	VP	HIP	ESC	PYRA	AGAL	BGUR	BGAL	PAL	LAP	ADH	RIB	ARA	MAN	SOR	LAC	TRE	INU	RAF	AMD	GLYG	HEM
Abiotrophia defectiva	25	0	15	**99**	**100**	0	**100**	0	**92**	0	0	0	0	0	**98**	**100**	5	**92**	**99**	0	0
Aerococcus urinae	3	**99**	24	12	0	**52**	**41**	**50**	**92**	28	28	0	**32**	13	**56**	**64**	1	1	**40**	0	0
Aerococcus viridans 1	13	**50**	**96**	**54**	**33**	16	**37**	1	5	1	**83**	**33**	**85**	**70**	**83**	**99**	**33**	**41**	**70**	**33**	1
Aerococcus viridans 2	15	**70**	**50**	**76**	10	20	25	1	5	5	25	1	**35**	2	**70**	**89**	1	5	24	1	5
Aerococcus viridans 3	22	**88**	**99**	**40**	**85**	**48**	14	14	1	1	8	2	**82**	5	**91**	**99**	**37**	**99**	14	1	1
Alloiococcus otitis	0	25	0	**100**	0	3	**100**	1	**90**	0	0	0	0	0	0	20	0	0	0	0	0
Enterococcus avium	**99**	**60**	**99**	**94**	15	0	24	1	**99**	0	**99**	**40**	**100**	**95**	**95**	**99**	1	**40**	15	0	1
Enterococcus durans	**100**	**43**	**100**	**97**	**32**	2	**76**	1	**91**	**100**	**99**	15	2	0	**84**	**76**	0	0	**56**	0	18
Enterococcus faecalis	**99**	**46**	**99**	**97**	1	0	21	4	**99**	**92**	**98**	1	**98**	**92**	**92**	**100**	0	1	**96**	2	1
Enterococcus faecium *	**94**	**43**	**99**	**95**	**42**	1	**89**	1	**97**	**93**	**85**	**70**	**78**	18	**84**	**98**	15	10	**60**	3	1
Gardnerella vaginalis	0	**95**	0	1	0	1	**53**	0	**99**	0	**46**	6	1	0	1	0	0	0	**73**	**53**	0
Gemella haemolysans	25	0	0	**70**	0	0	1	**84**	**40**	1	1	0	20	10	5	2	0	0	10	5	1
Gemella morbillorum	3	0	0	**35**	0	0	10	**35**	**86**	4	5	0	1	0	1	11	3	1	16	5	0
Globicatella sanguinis	4	**40**	**98**	**40**	**52**	16	**100**	0	9	0	**76**	**95**	**71**	**47**	**76**	**100**	**71**	**95**	**100**	**90**	0
Granulicatella adiacens	0	0	10	**80**	0	25	0	0	**99**	0	0	0	0	0	0	0	0	0	0	0	0
Lactococcus lactis ssp *cremoris*	**98**	**25**	**41**	1	23	0	18	4	**88**	0	**27**	0	17	0	**97**	**30**	0	15	25	0	0
Lactococcus lactis ssp *lactis*	**90**	**40**	**99**	**35**	3	0	**35**	3	**96**	**95**	**95**	15	**45**	1	**72**	**87**	4	5	**90**	3	1
Leuconostoc spp	**91**	1	**60**	5	**55**	0	**65**	2	**70**	10	**37**	**35**	**29**	4	**35**	**65**	0	**42**	11	0	0
Listeria spp	**97**	**79**	**98**	0	0	0	0	0	**85**	0	6	0	0	0	**49**	**92**	1	1	**72**	0	**26**
Streptococcus agalactiae **	**100**	**99**	1	1	4	**79**	1	**96**	**99**	**99**	**98**	0	1	1	**50**	**87**	0	1	**35**	4	**75**
Streptococcus anginosus	**100**	0	**100**	0	**44**	0	1	**99**	**100**	**100**	0	0	**33**	0	**99**	**88**	0	**44**	**97**	0	**37**
Streptococcus bovis I	**99**	1	**100**	1	**34**	2	1	0	**100**	0	0	1	**97**	1	**100**	**100**	**65**	**98**	**98**	**98**	1
Streptococcus bovis II 1	**100**	0	1	0	**58**	0	0	0	**100**	0	0	0	0	0	**90**	0	0	**97**	**97**	**97**	0
Streptococcus bovis II 2	**100**	2	**100**	0	**89**	**97**	**99**	0	**100**	0	0	0	0	0	**100**	**100**	0	**72**	**31**	5	0
Streptococcus bovis II 3	**99**	1	**100**	0	**99**	0	6	0	**100**	0	0	0	0	0	**100**	6	6	**100**	**93**	0	0
Streptococcus bovis II 4	**98**	1	**100**	0	**97**	2	10	0	**100**	1	1	**32**	1	1	**98**	**40**	**84**	**99**	**99**	**97**	0
Streptococcus canis	0	1	25	4	**95**	1	**80**	**100**	**100**	**100**	**100**	0	0	0	**99**	1	0	1	**99**	0	**100**
Streptococcus constellatus	**100**	1	**27**	0	0	0	5	**99**	**100**	**100**	0	0	0	0	10	**72**	0	0	12	0	**61**
*Streptococcus dys.*ssp *dysgalactiae*	0	0	1	1	1	**99**	0	**100**	**99**	**100**	**99**	0	1	**50**	**86**	**100**	0	1	**99**	**30**	2
*Streptococcus dys.*ssp *equisimilis*	0	1	25	1	1	**99**	1	**99**	**100**	**97**	**97**	1	1	1	**45**	**99**	0	1	**98**	**40**	**94**
Streptococcus equi ssp *equi*	1	0	1	0	0	**100**	0	**100**	**100**	**100**	0	0	0	0	0	1	0	0	**100**	**100**	**100**
Streptococcus equi ssp *zooepidemicus*	0	1	15	0	0	**100**	1	**99**	**100**	**99**	**85**	0	0	**99**	**100**	0	0	0	**99**	**99**	**99**
Streptococcus equinus	**100**	0	**95**	0	**28**	0	1	1	**100**	0	0	0	**30**	0	25	7	25	15	17	10	0
Streptococcus group L	1	**75**	1	0	0	**100**	1	**100**	**100**	**100**	**100**	0	0	0	**75**	**100**	0	0	**100**	**98**	**94**
Streptococcus intermedius	**100**	0	**87**	0	0	0	**44**	**99**	**100**	**100**	0	0	0	0	**99**	**99**	3	3	**99**	0	**40**
Streptococcus mitis 1	1	0	3	1	21	0	25	**35**	**99**	19	14	1	0	1	**94**	7	3	**26**	**67**	5	0
Streptococcus mitis 2	0	0	3	0	**31**	0	**35**	**50**	**100**	**99**	1	0	1	0	**100**	1	1	**31**	**84**	0	0
Streptococcus mutans	**99**	0	**99**	1	**64**	0	1	1	**100**	18	0	0	**99**	**90**	**90**	**100**	**81**	**81**	1	0	1
Streptococcus oralis	0	0	1	1	**50**	0	**46**	**72**	**100**	5	1	0	1	0	**99**	**32**	1	**72**	**96**	0	0
Streptococcus pneumoniae	0	0	**39**	**60**	**70**	3	**79**	3	**100**	**57**	3	1	0	0	**99**	**98**	**64**	**87**	**84**	10	1
Streptococcus porcinus	**100**	5	**99**	1	19	**99**	1	**97**	**97**	**100**	**98**	0	**88**	**88**	**83**	**99**	0	0	**50**	0	**100**
Streptococcus pyogenes	0	1	5	**98**	0	15	0	**100**	**100**	**99**	0	0	8	1	**99**	**98**	0	1	**61**	22	**98**
Streptococcus salivarius	**85**	0	**98**	1	8	0	**70**	20	**100**	0	0	0	5	1	**86**	**67**	**34**	**88**	**74**	1	1
Streptococcus sanguinis	0	1	**42**	0	**63**	0	1	5	**100**	**90**	0	0	1	**48**	**83**	**98**	**33**	**55**	**67**	0	0
Streptococcus suis I	0	1	**82**	**53**	**80**	**94**	**76**	1	**100**	**91**	0	0	7	0	**94**	**100**	**75**	0	**100**	**89**	0
Streptococcus suis II	0	1	**70**	**41**	**91**	**91**	**52**	3	**100**	**95**	0	0	3	1	**99**	**98**	**63**	**93**	**99**	**96**	2
Streptococcus uberis	**99**	**98**	**100**	**35**	10	**86**	5	**30**	**100**	**98**	**99**	0	**99**	**98**	**99**	**99**	**87**	10	**50**	20	0

* si / if / wenn / se / εάν / om / hvis / gdy : *VancoR / VanR / VAN = R :* { *Enterococcus casseliflavus* ou / or / od. / o / ή / eller / lub *Enterococcus gallinarum* } possible / möglich / posible / possibile / possível / πιθανόν / möjlig / mulig / możliwość.

** 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. APPELBAUM P.C., CHAURUSHIYA P.S., JACOBS M.R., DUFFETT A.
   Evaluation of the Rapid Strep System for Species Identification of Streptococci.
   (1984) J. Clin. Microbiol., 19, 588-591.
2. BALL L.C., COLMAN G.
   A Comparison of Conventional Methods and API Galleries for the Identification of Streptococci.
   (1982) International Meeting on Streptococci and Streptococcal Diseases, LUND SWEDEN, 41-42.
3. BANNISTER M.F., BENSON C.E. and SWEENEY C.R.
   Rapid Species Identification of Group C Streptococci Isolated from Horses.
   (1985) J. Clin. Microbiol., 21, 524-526.
4. COLMAN G., BALL L.C.
   Identification of Streptococci in a Medical Laboratory.
   (1984) J. Appl. Bact., 57, 1-14.
5. FACKLAM R.R., RHODEN D.L., SMITH P.B.
   Evaluation of the Rapid Strep System for the Identification of Clinical Isolates of *Streptococcus* Species.
   (1984) J. Clin. Microbiol., 20, 894-898.
6. HUMAN R.P. and TILLOTSON G.S.
   Identification of *Gardnerella vaginalis* with the API 20 Strep System.
   (1985) J. Clin. Microbiol., 21, 985-986.
7. KLOOSTERMAN R.E., CULLEN K.D., McCLATCHEY K.D.
   Comparison of Two Commercial Systems for the Rapid Identification of Streptococci.
   (1984) ASM ST. LOUIS C198.
8. MacGOWAN A.P., MARSHALL R.J., REEVES D.S.
   Evaluation of API 20 STREP System for Identifying *Listeria* Species.
   (1989) J. Clin. Path., 42, 548-550.
9. RUOFF K.L., KUNZ L.J.
   Use of the Rapid STREP System for Identification of Viridans Streptococcal Species.
   (1983) J. Clin. Microbiol., 18, 1138-1140.
10. TILLOTSON G.S.
    An Evaluation of the API 20 Strep System.
    (1982) J. Clin. Path., 468-472.
11. Clinical and Laboratory Standards Institute, M50-A Quality Control for Commercial Microbial Identification Systems; Approved Guideline, Vol. 28 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
REF	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
IVD	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 limitation Temperaturbegrenzung / Límite de temperatura Limiti di temperatura / Limites de temperatura Περιορισμοί θερμοκρασίας / Temperaturbegränsning Temperaturbegrænsning / Przestrzegać zakresu temperatury
	Utiliser jusque / Use by / Verwendbar bis Fecha de caducidad / Utilizzare entro / Prazo de validade Ημερομηνία λήξης / Använd före / Holdbar til / Użyć przed
LOT	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
	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

BIOMÉRIEUX

bioMérieux SA
RCS LYON 673 620 399
69280 Marcy-l'Etoile / France
Tél. 33 (0)4 78 87 20 00
Fax 33 (0)4 78 87 20 90
www.biomerieux.com

bioMérieux, Inc
Box 15969,
Durham, NC 27704-0969 / USA
Tél. (1) 919 620 20 00
Fax (1) 919 620 22 11
Imprimé en / Printed in France

CE