

# api® 20 NE

IVD

Identification system for non-fastidious, non-enteric Gram-negative rods

## SUMMARY AND EXPLANATION

API 20 NE is a standardized system for the identification of non-fastidious, non-enteric Gram-negative rods (e.g. *Pseudomonas*, *Acinetobacter*, *Flavobacterium*, *Moraxella*, *Vibrio*, *Aeromonas*, etc.), combining 8 conventional tests, 12 assimilation tests and a 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 this package insert.

## PRINCIPLE

The API 20 NE strip consists of 20 microtubes containing dehydrated substrates.

The conventional tests are inoculated with a saline bacterial suspension which reconstitutes the media. During incubation, metabolism produces color changes that are either spontaneous or revealed by the addition of reagents.

The assimilation tests are inoculated with a minimal medium and the bacteria grow if they are capable of utilizing the corresponding substrate.

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 NE strips
- 25 incubation boxes
- 25 ampules of API AUX Medium
- 25 result sheets
- 1 package insert

## COMPOSITION

### Strip

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

### Medium

<b>API AUX Medium</b>	Ammonium sulphate	2 g
7 ml	Agar	1.5 g
	Vitamin solution	10.5 ml
	Trace elements	10 ml
	Monosodium phosphate	6.24 g
	Potassium chloride	1.5 g
	Demineralized water to make 1000 ml	
	Final pH : 7.0-7.2	

## REAGENTS AND MATERIAL REQUIRED BUT NOT PROVIDED

### Reagents :

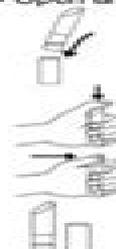
- API NaCl 0.85 % Medium, 2 ml (Ref. 20 070)
- Reagents : JAMES (Ref. 70 542)
- NIT 1 + NIT 2 (Ref. 70 442)
- Zn (Ref. 70 380)
- Oxidase (Ref. 55 635\*)
- \* reference not sold in certain countries : use an equivalent reagent.
- Mineral oil (Ref. 70 100)
- McFarland Standard (Ref. 70 900) No. 0.5
- API 20 NE Analytical Profile Index (Ref. 20 050) or identification software (consult bioMérieux)

### Material :

- Pipettes or PSlipettes
- Ampule protector
- Ampule rack
- 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 "NCCCLS M29-A, Protection of Laboratory Workers from Injuries Transmitted by Blood, Body Fluids, and Tissue; Approved Guideline - December 1997". For additional handling precautions, refer to "Biosafety in Microbiological and Biomedical Laboratories, HHS Publication No. (CDC) 93-8395, 3rd Edition (May 1993)", or to the regulations currently in use in each country.
- Do not use reagents past the expiration date.
- Before use, check that the packaging and components are intact.
- Do not use strips which have been damaged : cupules deformed, 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.
- Cover the flattened part of the cap with the upper part of the thumb.
- Apply thumb pressure in an outward motion to the base of the flattened part of the cap to snap off the top of the ampule inside the cap.
- 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.

# Api 20e Manual

**American Society for Microbiology**



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