

**REF 20040 / 20070 / 20230**

11791 - D - 2020/05

**EN**

**REF 20150 / 70640 / 70700**

## API® NaCl 0.85 % Medium API® Suspension Medium

Media for the preparation of organism suspensions

**Rx only**

**IVD**

### INTENDED USE

API® NaCl 0.85 % Medium and API® Suspension Medium are designed to be used as suspension media with API®, ID 32 or ATB™ products, in the conditions defined in the package inserts of these products.

### CONTENT OF THE KIT

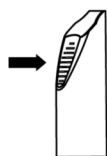
- 100 ampules
- 1 package insert provided in the kit or downloadable from [www.biomerieux.com/techlib](http://www.biomerieux.com/techlib)

### COMPOSITION

<b>API® NaCl 0.85 % Medium</b> 2 mL (Ref 20070) 3 mL (Ref 20040) 5 mL (Ref 20230)	Sodium chloride	8.5 g
	Demineralized water	1000 mL
<b>API® Suspension Medium</b> 2 mL (Ref 70700) 3 mL (Ref 70640) 5 mL (Ref 20150)	Demineralized water	

### WARNINGS AND PRECAUTIONS

- **For *in vitro* diagnostic use and microbiological control.**
- **For professional use only.** This test is intended for use by trained laboratory professionals.
- **For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.**
- Do not use media after the expiry date.
- Upon receipt, discard any kits which are visibly deteriorated: for example, damaged packaging, stains.
- The media are for single use only and should not be reused.
- Allow media to come to room temperature before use.
- 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.
- 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.



### STORAGE CONDITIONS

- The media should be stored at +2°C/+30°C until the expiry date indicated on the ampule label.
- After opening the kit, check that the ampules are intact. If any ampules are broken, the kit must be disposed of in an appropriate container.

## 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

1. LE MINOR L., VERON M., Bactériologie Médicale, 2ème édition, (1989) Flammarion Médecine Sciences.

## INDEX OF SYMBOLS

Symbol	Meaning
	Catalog number
	<i>In Vitro</i> Diagnostic Medical Device
	For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner
	Manufacturer
	Temperature limit
	Use by date
	Batch code
	Do not re-use
	Consult Instructions for Use
	Contains sufficient for <n> tests
	Date of manufacture

## 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, bioMérieux 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.

**For more detailed information, consult the package insert of the strips with which the media are used.**

**REVISION HISTORY**

## Change type categories

N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical	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
2020/05	11791D	Administrative	Improvements to match the bioMérieux templates and style guide and comply with the IVDR (EU) 2017/746 regulation.

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CLSI is a trademark belonging to Clinical Laboratory and Standards Institute, Inc.

Any other name or trademark is the property of its respective owner.

For users in the European Union (Regulation (EU) 2017/746) and in countries with similar requirements: Should a serious incident occur during the use of this device or as a result of its use, please report it to the manufacturer and/or their authorized representative as well as to your national authority.