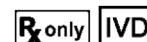


REF	70380 Zn (x2)
REF	70402 TDA (x2)
REF	70542 JAMES (x2)
REF	70422 VP 1 (x2) + VP 2 (x2)
REF	70442 NIT 1 (x2) + NIT 2 (x2)
REF	20120 API® 20 E REAGENTS

Reagents



PRODUCTS AND ASSOCIATED REAGENTS

JAMES	API® NH (10400), API® 20 E (20100/20160), API® 10 S (10100), RAPID 20 E™ (20701), API® 20 NE (20050), ID 32 E (32400), RAPID ID 32 A (32300), RAPID ID 32 E (32700)	
NIT 1	API® 20 E (20100/20160), API® 10 S (10100), API® 20 NE (20050), API® STAPH (20500), API® CORYNE (20900), API® CAMPY (20800), ID 32 STAPH (32500), RAPID ID 32 A (32300)	
NIT 2	API® 20 E (20100/20160), API® 10 S (10100), API® 20 NE (20050), API® STAPH (20500), API® CORYNE (20900), API® CAMPY (20800), ID 32 STAPH (32500), RAPID ID 32 A (32300)	
TDA	API® 20 E (20100/20160), API® 10 S (10100)	
VP 1	API® 20 E (20100/20160), RAPID 20 E™ (20701), API® STAPH (20500), API® 20 STREP (20600)	
VP 2	API® 20 E (20100/20160), RAPID 20 E™ (20701), API® STAPH (20500), API® 20 STREP (20600)	
Zn	API® 20 E (20100/20160), API® 20 NE (20050)	
API® 20 E Reagent kit (20120) JAMES + NIT 1 + NIT 2 + TDA + VP 1 + VP 2		API® 20 E (20100/20160)

COMPOSITION OF THE REAGENTS

JAMES 5 mL R2: WARNING * SGH07	R1: HCl 1N R2: Compound J 2183 (confidential) H315 / H319 / H335 / P261 / P280 / P302+P352 / P305+P351+P338	100 mL 0.66 g
NIT 1 5 mL DANGER * SGH05	Sulfanilic acid Acetic acid H ₂ O H314 / P260 / P280 / P305+P351+P338 / P337+P313	0.4 g 30 g 70 mL
NIT 2 5 mL DANGER * SGH05	N,N-dimethyl-1-naphthylamine Acetic acid H ₂ O H314 / P260 / P280 / P305+P351+P338 / P337+P313	0.6 g 30 g 70 mL
TDA 5 mL R2: DANGER * SGH05 – SGH07	Ferric chloride (iron content) H ₂ O H302 / H315 / H318 / H412 / P273 / P280 / P305+P351+P338 / P302+P352	3.4 g 100 mL
VP 1 5 mL DANGER * SGH05 – SGH07	Potassium hydroxide H ₂ O H302 / H314 / P280 / P305+P351+P338 / P337+P313 / P302+P352	40 g 100 mL
VP 2 5 mL DANGER * SGH02 - SGH05 – SGH07	α-naphthol Ethanol H225 / H312 / H318 / P210 / P280 / P305+P351+P338 / P403	6 g 100 mL
Zn 10 g WARNING * SGH09	Zinc dust H400 / H410 / P260 / P280 / P273	

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

* Signal word:

SGH02	SGH05	SGH07	SGH09
			

For further information, consult the Safety Data Sheet.

HAZARD STATEMENTS

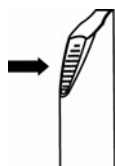
H225	Highly flammable liquid and vapour.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

PRECAUTIONARY STATEMENTS

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P273	Avoid release to the environment.
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.
P337+P313	If eye irritation persists: Get medical advice/attention.
P403	Store in a well-ventilated place.

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.
- **Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.**
- Refer to the hazard statements "H" and the precautionary statements "P" indicated above.
- Do not allow reagents to come into contact with skin, eyes or clothing.
- Do not use reagents after the expiry date.
- Before use, check that the packaging and components are intact.
- Allow reagents 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.

* For ampule with no dropper cap:

- Carefully remove the cap.

* For ampule with dropper cap:

- Turn the ampule upside down and maintain it in a vertical position
- Gently squeeze the cap to release a drop of reagent.

NOTE: For subsequent use, it is recommended to squeeze the cap before turning the ampule upside down in order to suck back any spare drops of reagent and thus avoid sprinkling cap or fingers with the reagent.

STORAGE CONDITIONS

STORAGE CONDITIONS	In the dark	TDA / VP 1 / VP 2 / NIT 1 / NIT 2 / R1 and R2 of JAMES / API® 20 E Reagent kit
STORAGE TEMPERATURE	+2°C/+8°C	VP 2 / NIT 2 / R2 of JAMES / API® 20 E Reagent kit
	+2°C/+30°C	TDA / VP 1 / NIT 1 / R1 of JAMES
	+8°C/+30°C	Zn
STORAGE BEFORE OPENING		Until the expiry date
STORAGE AFTER OPENING (1) AND TRANSFER (except the non-transferable reagents in the API® 20 E Reagent kit)		1 MONTH (without exceeding the expiry date)
REAGENTS SENSITIVE TO LIGHT (2)		JAMES / VP 2

- (1) **Record the opening date on the vial or ampule label.**
- (2) Check the appearance of the reagent before transferring it into the dropper vial. After transferring the contents of the ampule into the dropper vial, wrap the vial in aluminium foil.

APPEARANCE OF REAGENTS	
JAMES	R1: Clear liquid – colorless R2: Before reconstitution: whitish to yellowish After reconstitution: yellow
NIT 1	Clear liquid – colorless
NIT 2	Clear liquid – colorless
TDA	Clear liquid – orangey yellow
VP 1	Clear liquid – colorless
VP 2	Clear liquid – light pink (*)

(*) The shades of color may become deeper over time.

Important: make sure that the reagents are returned to the refrigerator immediately after use.

USE OF THE REAGENTS

Allow reagents to come to room temperature before use.

API® 20 E Reagent kit:

1. Open the ampules of reagents as indicated in the "Warnings and Precautions" paragraph (ampule with dropper cap).

TDA, VP 1, VP 2, NIT 1, NIT 2:

1. Open the ampule of reagent and transfer the contents into the dropper vial as indicated in the "Warnings and Precautions" paragraph (ampule with dropper cap).
2. Dispense one drop of reagent.
3. Carefully close the vial after use and store it as indicated in the "Storage conditions" paragraph.

JAMES:

1. Open the ampule of solvent associated with the JAMES reagent (R1) as indicated in the "Warnings and Precautions" paragraph (ampule with no dropper cap).
2. Take up the contents of the ampule using a completely dry pipette and transfer this solvent into the dropper vial (R2).
3. Fit the dropper to the vial.
4. Carefully close the vial.
5. Shake (as the vial contains the dehydrated active ingredient).
6. Wait approximately 10 minutes until the active ingredient has completely dissolved.
7. Use the reagent thus reconstituted, carefully close the vial and store it as indicated in the "Storage conditions" paragraph.

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.

Zn:

1. Open the vial.
2. Take up an aliquot of powder (approximately 2-3 mg) using the spatula fixed to the cap and deposit this quantity in the reaction cupule.
3. Carefully close the vial after use and store it as indicated in the "Storage conditions" paragraph.

WASTE DISPOSAL

Dispose of all used reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.











Dispose of unused reagents following procedures for hazardous chemical waste.

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. MacFADDIN J.F., Biochemical Tests for Identification of Medical Bacteria, Third Edition, (2000) Williams & Wilkins – Baltimore USA - ISBN 0-683-05318-3.

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
	Consult Instructions for Use
	Keep away from light
	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 reagents 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
2020/04	15460I	Administrative	Improvements to match the bioMérieux templates and style guide and comply with the IVDR (EU) 2017/746 regulation.

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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.