



Please distribute the attached customer letter.
To the Laboratory Manager
To the attention of the Healthcare center Chairman

Address
City, Date

Our reference: FSCA 5387

IMPORTANT:

URGENT FIELD SAFETY NOTICE

RAPID 20 E™ (Reference 20701)

Error on Package Insert (version G)

Dear valued bioMérieux Customer,

This letter is intended for RAPID 20 E™ (Reference 20701) users and our records indicate that your laboratory has received one of the lot numbers listed below:

Product Name	Reference	Lot number	Expiry date
RAPID 20 E™	20701	1008332150	20 April 2022
RAPID 20 E™	20701	1008787180	12 Dec 2022

Description of the issue

RAPID 20 E™ is a qualitative standardized system for the identification of *Enterobacteriaceae* in 4 hours, which uses 20 miniaturized biochemical tests chosen for their highly discriminant value and adapted to rapid interpretation. Inoculation and reading of the strip are performed manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure - Information for Identification Software.

Following a customer complaint, an error in the RAPID 20 E™ package insert version G has been confirmed.

In version G, Reading and Interpretation section, Reading Table, page 6, the negative CIT test result is stated as "Yellow" instead of "yellow to yellow- green". The previous version (version F) of the package insert for RAPID 20 E™ is correct.

Please see below correct and incorrect reading tables illustrating this error:

Subsidiary name (if applicable) / Nom de la filiale (si approprié)



* **Correct Reading Table:** 20701, RAPID 20 E™ package insert (version F):

READING TABLE

TESTS	ACTIVE INGREDIENTS	QTY (mg/cup.)	REACTIONS/ENZYMES	RESULTS	
				NEGATIVE	POSITIVE
ONPG	2-nitrophenyl-βD-galactopyranoside	0.076	βD-galactosidase (Ortho-NitroPhenyl-βD-Galactopyranosidase)	colorless	pale yellow to bright yellow
LDC	L-lysine	0.46	Lysine DeCarboxylase	yellow-green to bluish-grey	blue to blue-violet
ODC	L-ornithine	0.28	Ornithine DeCarboxylase	yellow-green to bluish-grey	blue to blue-violet
URE	urea	0.32	UREase	yellow	pink / pink-violet
CIT	trisodium citrate	0.132	CITrate utilization	yellow to yellow-green	green to blue

* **Incorrect Reading Table:** 20701, RAPID 20 E™ package insert (version G):

READING TABLE

TESTS	ACTIVE INGREDIENTS	QTY (mg/cupule)	REACTIONS/ENZYMES	RESULTS	
				NEGATIVE	POSITIVE
ONPG	2-Nitrophenyl-D-galactopyranoside	0.076	βD-Galactosidase (ortho-nitrophenyl-βD-galactopyranosidase)	Colorless	Pale yellow to bright yellow
LDC	L-Lysine	0.46	Lysine decarboxylase	Yellow-green to bluish-grey	Blue to blue-violet
ODC	L-Ornithine	0.28	Ornithine decarboxylase	Yellow-green to bluish-grey	Blue to blue-violet
URE	Urea	0.32	Urease	Yellow	Pink/Pink-violet
CIT	Trisodium citrate	0.132	Citrate utilization	Yellow	Green to blue

Impact to customer:

The error in the package insert for the CIT test could lead to difficulties in interpretation and in the worst case false positive results for this test, thus possibly no identification (delayed results) or identification errors with the 2 lots of RAPID 20 E™ mentioned above.

Required actions:

We request that you perform the following actions at this time:

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.
- **You can continue to use RAPID 20 E™ however, you must refer to the following Reading Table or to the corrected RAPID 20 E™ package insert version “G1” available on Resource Center when reading the CIT test result.**

READING TABLE

TESTS	ACTIVE INGREDIENTS	QTY (mg/cup.)	REACTIONS/ENZYMES	RESULTS	
				NEGATIVE	POSITIVE
CIT	trisodium citrate	0.132	CITrate utilization	yellow to yellow-green	green to blue

Subsidiary name (if applicable) / Nom de la filiale (si approprié)



- For tests previously performed using RAPID 20 E™, we strongly recommend that you identify any possible misidentifications, to analyze the related risks and to determine appropriate actions, if relevant.
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice.

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Thank you for your continued use of bioMérieux products,

bioMérieux, Inc.

[\[Enter Local Contact\]](#)

Subsidiary name (if applicable) / Nom de la filiale (si approprié)



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5387- RAPID 20 E™ Ref. 20701 – Error on Package Insert (version G)

TO BE RETURNED TO YOUR BIO-MERIEUX CUSTOMER SERVICE AT THE FOLLOWING

FAX NUMBER : XXXXXXXX

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “RAPID 20 E™ Ref. 20701 – Error on Package Insert (version G)
- I will implement the required actions indicated in the Urgent Field Safety Notice.
- Have you encountered impact on patients’ results, or reports of illness or injury related to the identified issue ?
 - Yes No Not applicable

DATE

SIGNATURE :

Subsidiary name (if applicable) / Nom de la filiale (si approprié)