



Medical Customer Letter

Please distribute the attached customer letter.

To the Laboratory Manager

To the attention of the Healthcare center Chairman

To the attention of the Reactovigilance correspondent

Address
City, Date

Our reference: **FCA 3206**

IMPORTANT:

PRODUCT CORRECTION NOTICE

**Etest® COLISTIN CO256 WW
(Ref.537300-537308)**

Dear bioMérieux Customer,

Our records indicate that your laboratory has received the following products. This letter is intended for all Etest® COLISTIN CO256 WW (Ref. 537300-537308) users (product reference and lot numbers included below).

This Product Correction Notice is a Follow-up of the FSCA#3061.

Table 1:

Reference	Description	Lot Number	Expiry date
537300	Etest®COLISTIN CO 256 WW B30	See Table 1 in annex	See Table 1 in annex
537308	Etest®COLISTIN CO 256 WW B100	See Table 1 in annex	See Table 1 in annex

Description of the issue

Based on the first results of investigations due to a potential underestimation of the MIC values for *Enterobacteriaceae* and *Acinetobacter*, **FSCA#3061** stating that **ETEST® COLISTIN CO256 WW (Ref.537300-Ref.537308) can only be used for diagnostic purposes with MH-E (Mueller Hinton-E agar from bioMérieux Ref. 413822-413823-413824-413825) agar for *Enterobacteriaceae* strains was issued on 25-JUL-2016.**

You received an associated customer letter informing you about the issue and introducing a restriction of ETEST® COLISTIN CO256 use accordingly:

“Therefore, for ***Enterobacteriaceae*** strains, you can continue to use **ETEST® COLISTIN CO256** (Ref. 537300- 537308)-lots listed Table 1 in annex of customer letter FSCA3061 **for diagnostic purposes, only if you use it with MH-E** (Mueller Hinton-E agar from bioMérieux Ref. 413822-413823-413824-413825) agar. **If not, or if you test other strains than**

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***Enterobacteriaceae* strains, we recommend you to restrict its use to epidemiological surveys."**

Since the last FSCA#3061, further investigations were performed and the potential hazards have been identified:

- ⇒ For ***Salmonella* strains that have not the mcr-1 gene**, in 20% of the cases, **there is a potential of Very Major Error (VME): Resistant gives Susceptible (R → S)** on ETEST® COLISTIN CO256 compared to the Broth Micro-dilution (BMD) method. **To be noted, there is no risk of VME for *Salmonella* strains that have the mcr1 gene in case of epidemiological use.**
- ⇒ For ***P.aeruginosa* strains**, there is a potential of VME Resistant gives Susceptible (R → S) for ***P.aeruginosa* strains** on ETEST® COLISTIN CO256 compared to BMD method. This potential issue was already corrected by FSCA#3061.
- ⇒ **There is a potential under-estimation of the MIC values for Susceptible *Enterobacteriaceae* strains.**

Impact to customer:

As the result of the referenced issue, the potential hazards:

1. **False Susceptible (S instead of R) results** with some Mueller Hinton agar (**except with the MHE agar from bioMérieux for the *Enterobacteriaceae* strains**) on ETEST® COLISTIN CO256. This risk identified and corrected by the FSCA#3061.
2. **False Susceptible (S instead of R) results** with ETEST® COLISTIN CO256 on **MH E (bioMérieux) agar** compared to the BMD method as reference for ***Salmonella* strains that have not the mcr-1 gene and for *P.aeruginosa* strains**
 - **As colistin is unlikely and should not be prescribed for cases of *Salmonella* infection, there is no impact of this new restriction in case of clinical use.**
 - The potential risk of False Susceptible result for ***P.aeruginosa* strains** has been already identified and corrected by FSCA#3061.
3. **Underestimation linked to low essential agreement of the MIC values for Susceptible *Enterobacteriaceae* strains**

Required actions:

- 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.
- **For diagnostic purposes**, you can continue to use ETEST® COLISTIN CO256 (Ref. 537300-537308)-lots listed Table 1 in annex, **only if you use it with MH-E agar** (Mueller Hinton-E agar from bioMérieux Ref. 413822-413823-413824-413825) **for *Enterobacteriaceae* (except for *Salmonella* strains) with the following recommendations:**
 - Categorization (Susceptible or Resistant) results need to be reported based on the EUCAST (S ≤2 mg/L et >2 mg/L R) critical concentrations.
 - **Due to the under-estimation of the MIC for *Enterobacteriaceae* Susceptible Strains, to verify the MIC of Susceptible strains as needed with the broth-micro dilution (BMD) method of reference before reporting results.**

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- **If you do not use Mueller Hinton-E agar** (from bioMérieux Ref. 413822-413823-413824-413825), **or if you test other strains, we recommend you to restrict its use to epidemiological surveys (as defined in the first FSCA#3061).**
In case of epidemiological use with other agars than MH-E (from bioMérieux), we recommend you to validate your agar before use.
- Among tests previously performed, we are asking you to identify any possible false Susceptible results, analyze the related risks and determine appropriate actions if relevant.
- Contact your local bioMérieux representative for product compensation.
- Complete and return the Acknowledgement Form in Attachment A by Fax 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.

Yours sincerely,
Medical Customer Service

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Attachment A: Acknowledgement Form.

PLEASE RETURN TO YOUR CUSTOMER SERVICE

Fax :

Name of the laboratory:

City:

Customer number:

I acknowledge the receipt of bioMérieux Product Correction Notice informing this laboratory on the Etest® COLISTIN CO256 WW (Ref. 537300-537308) product issue.

I have followed the instructions and implemented the actions as indicated in the Product Correction Notice.

Have you received reports of illness or injury related to the identified issue?

Yes or No

DATE

SIGNATURE :

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ANNEX : TABLE 1: LIST OF IMPACTED LOTS

Reference	Description	Lot Number	Expiry date
537300	Etest®COLISTIN CO 256 WW B30	1004970070	12-Jun-2021
		1004872780	18-Apr-2021
		1004861970	31-Mar-2021
		1004832200	31-Mar-2021
		1004752300	2-Mar-2021
		1004606550	5-Jan-2021
		1004523860	24-Nov-2020
		1004464760	1-Nov-2020
		1004437930	30-Sep-2020
		1004386240	12-Apr-2020
		1004329220	6-Sep-2020
		1004260630	25-Jul-2020
		1004190730	13-Jul-2020
		1004171220	6-Jul-2020
		1004129560	9-Jun-2020
		1004070260	20-May-2020
		1003969990	12-Apr-2020
		1003940910	15-Mar-2020
		1003890030	15-Mar-2020
		1003767080	20-Jan-2020
		1003725600	7-Jan-2020
		1003643960	2-Dec-2019
		1003610660	4-Nov-2019
		1003532330	17-Sep-2019
		1003514810	6-Oct-2019
		1003409250	23-Jul-2019
		1003297790	8-Jul-2019
		1003240130	20-May-2019
		1003146250	26-Mar-2019
		1003105550	26-Mar-2019
		1003052570	20-Mar-2019
		1002894460	18-Dec-2018
		1002849110	3-Dec-2018
1002816570	20-Nov-2018		
1002807980	15-May-2018		
1002780680	20-Nov-2018		
1002718610	15-Oct-2018		
1002594030	20-Aug-2018		

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	1004595380	5-Jan-2021
	1004542160	6-Dec-2020
	1004520890	24-Nov-2020
	1004442040	1-Nov-2020
	1004439600	30-Sep-2020
	1004329200	6-Sep-2020
	1004235390	13-Jul-2020
	1004177660	6-Jul-2020
	1004131970	9-Jun-2020
	1004075130	20-May-2020
	1003995330	12-Apr-2020
	1003946110	15-Mar-2020
	1003767090	20-Jan-2020
	1003728970	7-Jan-2020
	1003616140	17-Nov-2019
	1003532390	6-Oct-2019
	1003456440	17-Sep-2019
	1003403320	23-Jul-2019
	1003205800	23-Apr-2019
	1002989530	21-Jan-2019
	1002889130	18-Dec-2018
	1002795210	20-Nov-2018
	1002781850	17-Nov-2018
	1002703940	15-Oct-2018
	1002598660	20-Aug-2018
	1002523000	15-May-2018
	1002343060	16-Apr-2018
	1002273500	19-Feb-2018
	1002123620	6-Feb-2018
	1002089070	23-Jan-2018
	1002019130	7-Nov-2017
	1001965280	8-Oct-2017
	1001744750	24-Sep-2017
	1001721810	20-Jun-2017
	1001707310	20-Jun-2017
	1001634590	20-Jun-2017
	1001548430	14-May-2017
	1001548440	4-Jun-2017
	1001456040	14-May-2017
	1001417090	16-Apr-2017
	1001338250	16-Apr-2017

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		1001307480	16-Jan-2017
		1001307490	31-Jan-2017
		1001200010	31-Jan-2017
		1001183170	31-Jan-2017
		1001158910	15-Nov-2016
		1001142970	15-Nov-2016
		1001125540	23-Oct-2016
		1001032690	23-Oct-2016
		1001002040	25-Sep-2016
		1000924790	25-Sep-2016
		1000908060	7-Sep-2016
		1000756340	20-Aug-2016
		1000750730	20-Aug-2016
		1000714710	20-Aug-2016

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