



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: FSCA 3061

IMPORTANT:

URGENT FIELD SAFETY NOTICE

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

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).

Product References impacted:

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 scientific publications (including EUCAST warning letter on their website) on colistin gradient and disk diffusion tests, including our Etest®COLISTIN (Ref. 537300- 537308)-lots listed in Table 1 in Annex, bioMérieux was alerted about a potential underestimation of the MIC values for *Enterobacteriaceae* and *Acinetobacter*, bioMérieux initiated a complaint investigation to confirm product performance and determine root cause. While the internal and external investigations are still ongoing, **to date and based on data available**, the following have been identified:

- ⇒ The Etest® COLISTIN CO256 performance are depending on the Mueller Hinton agar plate used as described in the Supplement Insert (Ref.16266, version A)- CIS012.
- ⇒ **For the *Enterobacteriaceae* strains, the first results of our investigation state that the performance of Etest® COLISTIN CO256 are conformed if used in conjunction with the MHE agar (from bioMérieux) with a good concordance rate compared to Broth-Micro Dilution (BMD) method.**

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- ⇒ There is a potential of **False Susceptible results** on Etest® COLISTIN CO256 WW (Ref. 537300-537308) with some Mueller Hinton agar (**except with the MHE agar from bioMérieux for the *Enterobacteriaceae* strains**).

- ⇒ These data need to be confirmed by the investigations ongoing.

Impact to Patient/User:

As the result of the referenced issue, the potential hazard is to obtain **False Susceptible (S instead of R) results with ETEST® COLISTIN CO256 on some Mueller Hinton agars (except on MHE for the *Enterobacteriaceae* strains) compared the Broth Micro-dilution (BMD) method as reference** (based on the investigation data available to date).

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.

- Therefore, for ***Enterobacteriaceae*** strains, you can continue to use **Etest® COLISTIN CO256** (Ref. 537300- 537308)-lots listed Table 1 in annex **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 *Enterobacteriaceae* strains, we recommend you to restrict its use to epidemiological surveys.**

- 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. **We will keep you informed as soon as possible of internal and external ongoing investigation results.**

Yours sincerely,
Medical Customer Service

Attachment A: Acknowledgement Form.

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PLEASE RETURN TO YOUR CUSTOMER SERVICE

Fax :

Name of the laboratory:

City:

Customer number:

I acknowledge the receipt of bioMérieux Urgent Field Safety 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 Urgent Field Safety 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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		1002517610	15-May-2018
		1002438560	16-Apr-2018
		1002336190	16-Apr-2018
		1002280740	12-Mar-2018
		1002154530	19-Feb-2018
		1002106970	23-Jan-2018
		1002053380	23-Jan-2018
		1001988910	7-Nov-2017
		1001920000	7-Nov-2017
		1001898050	7-Nov-2017
		1001742150	30-Jul-2017
		1001721800	30-Jul-2017
		1001687660	30-Jul-2017
		1001596380	30-Jul-2017
		1001567710	4-Jun-2017
		1001496190	14-May-2017
		1001496200	4-Jun-2017
		1001472220	4-Jun-2017
		1001417080	14-May-2017
		1001338240	16-Apr-2017
		1001317190	16-Jan-2017
		1001260560	16-Jan-2017
		1001158900	16-Jan-2017
		1001142860	15-Nov-2016
		1001032680	23-Oct-2016
		1001062860	15-Nov-2016
		1000941970	23-Oct-2016
		1000893880	25-Sep-2016
		1000756330	7-Sep-2016
		1000750130	7-Sep-2016
		1000746340	20-Aug-2016
		1000714690	20-Aug-2016
		1000651250	11-Jul-2016
		1000635770	11-Jul-2016
Reference	Product Name	Lot Number	Expiry date
537308	Etest®COLISTIN CO 256 WW B100	1004972220	12-Jun-2021
		1004864570	18-Apr-2021
		1004791040	31-Mar-2021
		1004752310	2-Mar-2021
		1004596710	5-Jan-2021

	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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