



1 August 2016

«Title_»
«andor_»
«Company_Name»
«Address_line_1»
«Address_line_2»
«Address_line_3»
«City»
«County»
«Postal_Code»

Our reference: FSCA 3061

Dear Sir / Madam

IMPORTANT: URGENT FIELD SAFETY NOTICE
ETEST® COLISTIN (CO 256) Ref: 537300 & 537308

This letter is intended for all ETEST® COLISTIN users, and our records indicate that your laboratory has received this product.

Product References impacted:

Reference	Description	Lot Number & Expiry Date
537300	ETEST COLISTIN (CO 256) WW B30	Please refer to Annex: Table 1: List of Impacted Lots
537308	ETEST COLISTIN (CO 256) WW B100	

Description of the issue

Based on scientific publications evaluating COLISTIN gradient strips and disk diffusion tests, bioMérieux was alerted to a potential underestimation of the MIC values for *Enterobacteriaceae* and *Acinetobacter* spp. when ETEST COLISTIN strips were used. This has led to the initiation of a complaint investigation to confirm product performance and determine any root cause. Although the internal and external investigations are still ongoing, **based on the data available to-date** we have identified the following:

- ⇒ The **performance** of ETEST COLISTIN strips is **dependent on the Mueller Hinton agar used**; this must have consistent and appropriate cation levels.
- ⇒ ETEST COLISTIN strips (from the lots listed in Table 1 in the annex) **performed well with *Enterobacteriaceae* spp. if used in conjunction with Mueller Hinton-E agar (MH-E) supplied by bioMérieux**; good concordance was found when compared with the Broth-Micro Dilution (BMD) method
- ⇒ There is a potential for **False Susceptible** results when ETEST COLISTIN strips are used in conjunction with **some Mueller Hinton agars**; this excludes *Enterobacteriaceae* spp. tested on MH-E agar supplied by bioMérieux.
- ⇒ **This data is preliminary and needs to be confirmed by the ongoing investigation**

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Impact to Patient/ User:

Based on the bioMérieux investigation data available to date, there is a **potential hazard to obtain a False Susceptible** (S instead of R) result when ETEST COLISTIN strips are used in conjunction with some Mueller Hinton agars.

This does not apply to ETEST COLISTIN strips used for the susceptibility testing of *Enterobacteriaceae* spp. when they are used in conjunction with MH-E agar manufactured by bioMérieux.

Required actions:

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy for your files, and forward this information to all parties that may use this product, including others to whom you may have transferred the product.
- For *Enterobacteriaceae* spp., you can continue to use ETEST COLISTIN strips for diagnostic purposes from the lots listed in Table 1 in the Annex, **only if you use them with MH-E agar supplied by bioMérieux** (Ref. 413822; 413824).
- For micro-organisms other than *Enterobacteriaceae* spp., we recommend that you restrict the use of ETEST COLISTIN strips to epidemiological surveys.
- If ETEST COLISTIN strips are used in conjunction with Mueller Hinton agar other than MH-E agar supplied by bioMérieux, we recommend that the results are restricted to epidemiological surveys.
- For tests previously performed, we are asking you to identify any possible False Susceptible results, analyse the related risks and determine appropriate actions if relevant.
- Contact your local bioMérieux representative if you would like to receive more information regarding MH-E agar.
- Complete the Acknowledgement Form in Attachment A and return for the attention of Sheila Marsh to fax number 0044 (0) 1256 816863 or scan and email to sheila.marsh@biomerieux.com to confirm receipt of this notice.

We can confirm that the Competent Authority has been informed of this notice.

bioMérieux is committed to providing our customers with the highest quality products possible, and we sincerely apologise for any inconvenience that this issue may cause you.

If you require additional assistance or have any questions, please contact our UK Technical Department (email: uktechnical@biomerieux.com).

We will notify you again once we have further findings following our ongoing internal and external investigations.

Yours sincerely

Customer Services Department





Attachment A: Acknowledgement Form.

**URGENT FIELD SAFETY NOTICE - FSCA 3061
E TEST® COLISTON (CO 256) Ref: 537300 & 537308**

In order to comply with Competent Authority Regulations it is important that you complete and return this acknowledgement form

**Please return for the attention of Customer Services to fax number
0044 (0) 1256 816863**

- «Title_»
- «andor_»
- «Company_Name»
- «Address_line_1»
- «Address_line_2»
- «Address_line_3»
- «City»
- «County»
- «Postal_Code»

I acknowledge the receipt of bioMérieux's Urgent Field Safety Notice informing this laboratory of 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

NAME :

SIGNATURE :

DATE :





Answered: A. [unclear]

URGENT FIELD SAFETY NOTICE - F82A 2011
F82A 2011 - URGENT FIELD SAFETY NOTICE

is a safety notice for the F82A 2011 product. It is intended to inform you of the safety issues associated with the use of this product.

For more information, please contact your local distributor or visit our website at www.biomerieux.com.

Product Name: F82A 2011
Product Code: F82A 2011
Product Description: [unclear]
Product Category: [unclear]
Product Status: [unclear]

If you have any questions or concerns regarding the safety of this product, please contact your local distributor or visit our website at www.biomerieux.com.

If you have any questions or concerns regarding the safety of this product, please contact your local distributor or visit our website at www.biomerieux.com.

For more information, please contact your local distributor or visit our website at www.biomerieux.com.

Product Name: F82A 2011

Product Code: F82A 2011

Product Description: [unclear]



ANNEX : TABLE 1: LIST OF IMPACTED LOTS

Reference	Description	Lot Number	Expiry date
537300	EATEST 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		

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		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

Reference	Description	Lot Number	Expiry date
537300	EATEST COLISTIN CO 256 WW B30	1002594030	20-Aug-2018
		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-017
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	Description	Lot Number	Expiry date
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537308	EATEST 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

Reference	Description	Lot Number	Expiry date
537308	EATEST COLISTIN CO 256 WW B100	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
		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		

PLATEAU 1000

Code	Description	Quantité	Unité
1000001
1000002
1000003
1000004
1000005
1000006
1000007
1000008
1000009
1000010
1000011
1000012
1000013
1000014
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