



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 :



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 | | |

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| | | 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 | | |

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| | | 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 | ETEST 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 | | |

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