

16 January 2017

Attachment 8

**URGENT FIELD SAFETY NOTICE
FSCA3193**

ETEST® Fosfomycin FM1024 (Ref. 529140, 529148, 529100, 529108) blister packaging

Dear

Our records indicate that your laboratory received the following products. This letter is intended for all ETEST® Fosfomycin FM1024 (Ref. 529140, 529148, 529100, 529108) blister packaging US & World Wide users. Product reference and lot numbers are included in Table 1 and Table 2.

Description of the issue:

As a part of our ongoing thorough analysis of the ETEST® product range, we have observed internally that current shelf-life claims of the ETEST® Fosfomycin FM1024 product listed in Table 1 and Table 2 are not supported by internal testing. No increase of the complaint trend was observed for these products, but we are taking the precaution of revising the shelf-life claims, that requires your immediate attention to ensure proper use of the product within its revised shelf-life of twenty four (24) months.

When used within the revised shelf-life, the product will continue to perform per its labeled performance specifications, the following have been identified:

- ⇒ QC failure (MICs above the upper QC limit) for some Quality Control strains listed in the Instructions For Use on ETEST® Fosfomycin FM1024 (Ref. 529140, 529148, 529100, 529108) blister packaging starting after 24 months of shelf-life

Impact:

As a result of the observed performance issue, there is a potential to obtain a MIC result that is higher than expected after 24 months of shelf-life. This type of error would be detectable during quality control testing as an out of range MIC result would be obtained. Patient results may also be elevated resulting in a false resistant result.

Required actions:

Product with NO remaining shelf life (after reduction):

- Identify impacted lots of **ETEST® Fosfomycin FM1024 (Ref. 529140, 529148, 529100, 529108) Blister** packaging (lots listed Table 1 below) which are now expired.
- Immediately order the replacement products appropriate for your institution.



- Laboratories should continue to follow their current QC procedures for **ETEST® Fosfomycin FM1024 (Ref. 529140, 529148, 529100, 529108)** lots listed in Table 1, in accordance with CLIA and local regulatory requirements, with a modification to increase the frequency of QC testing to weekly or every day of use if previous QC testing exceeds one week and only report results if the QC is in the acceptable range. Also, we recommend to include in the QC testing, the organisms defined as the stability indicators for ETEST® Fosfomycin FM1024 (Ref. 529140, 529148, 529100, 529108) that are *E coli* ATCC25922 (Expected range-MIC: 0.5-2 µg/mL) and *E.faecalis* ATCC 29212 (Expected range-MIC: 16-64µg/mL) strains. The MIC results for this specific strains must fall in the acceptable range to confirm the validity of the QC test and performance of the ETEST strip.
- If replacement product is received, discontinue using and discard impacted **ETEST® Fosfomycin FM1024 (Ref. 529140, 529148, 529100, 529108)** lots listed in Table 1.

Product with remaining shelf life:

- Identify impacted lots defined in Table 2, which may be used within the revised shelf life requirements as defined in Table 2.
- Update the expiration date of the remaining usable product to meet the new shelf life specified in Table 2.

Additional 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.
- Please work with your institution's risk management team to determine if retrospective analysis of results is required for your patients.
- Complete and return the Acknowledgement Form in Attachment A for the attention of Customer Service Department to fax number 0044 (0) 1256 816863 to confirm receipt of this notice.

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologise for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact our Technical Service Department on 0044 (0) 1256 461881.

Yours sincerely

Customer Service Department



Table 1: Product with NO remaining shelf life (after reduction). QC testing required.

REF	Lot#	Product Name	Current Shelf Life	Corrected Shelf Life	Corrected Expiration Date
529100	1001324170	FM1024 (B) WW	60	24	22-Mar-2014
529100	1001378120	FM1024 (B) WW	60	24	22-Mar-2014
529100	1001403920	FM1024 (B) WW	60	24	22-Mar-2014
529100	1001433710	FM1024 (B) WW	60	24	22-Mar-2014
529100	1001472010	FM1024 (B) WW	60	24	22-Mar-2014
529100	1001487340	FM1024 (B) WW	60	24	22-May-2014
529100	1001517680	FM1024 (B) WW	60	24	22-May-2014
529100	1001535750	FM1024 (B) WW	60	24	22-May-2014
529100	1001567600	FM1024 (B) WW	60	24	22-May-2014
529100	1001617880	FM1024 (B) WW	60	24	22-May-2014
529100	1001621170	FM1024 (B) WW	60	24	22-May-2014
529100	1001702730	FM1024 (B) WW	60	24	22-May-2014
529100	1001707190	FM1024 (B) WW	60	24	22-May-2014
529100	1001726300	FM1024 (B) WW	60	24	27-Aug-2014
529100	1001761020	FM1024 (B) WW	60	24	27-Aug-2014
529100	1001879240	FM1024 (B) WW	60	24	13-Nov-2014
529100	1001927370	FM1024 (B) WW	60	24	13-Nov-2014
529100	1001976740	FM1024 (B) WW	60	24	13-Nov-2014
529100	1001998470	FM1024 (B) WW	60	24	13-Nov-2014
529100	1002123080	FM1024 (B) WW	60	24	13-Nov-2014
529100	1002160660	FM1024 (B) WW	60	24	27-Feb-2015
529100	1002391350	FM1024 (B) WW	60	24	27-Feb-2015
529100	1002449230	FM1024 (B) WW	60	24	25-Jun-2015
529100	1002487920	FM1024 (B) WW	60	24	10-Jul-2015
529100	1002551790	FM1024 (B) WW	60	24	22-Jul-2015
529100	1002614480	FM1024 (B) WW	60	24	22-Aug-2015
529100	1002705810	FM1024 (B) WW	60	24	25-Sep-2015
529100	1002786510	FM1024 (B) WW	60	24	7-Nov-2015
529100	1002890670	FM1024 (B) WW	60	24	10-Jul-2015
529100	1002960380	FM1024 (B) WW	60	24	16-Jan-2016
529100	1002992220	FM1024 (B) WW	60	24	20-Feb-2016
529100	1003030800	FM1024 (B) WW	60	24	6-Mar-2016
529100	1003181900	FM1024 (B) WW	60	24	15-May-2016
529100	1003274090	FM1024 (B) WW	60	24	25-Jun-2016
529100	1003491050	FM1024 (B) WW	60	24	18-Sep-2016
529100	1003526870	FM1024 (B) WW	60	24	8-Oct-2016
529100	1003557650	FM1024 (B) WW	60	24	23-Oct-2016
529100	1003678050	FM1024 (B) WW	60	24	4-Dec-2016



529108	1001324180	FM1024 (B) WW	60	24	22-Mar-2014
529108	1001370190	FM1024 (B) WW	60	24	22-Mar-2014
529108	1001482570	FM1024 (B) WW	60	24	22-Mar-2014
529108	1001527650	FM1024 (B) WW	60	24	22-Mar-2014
529108	1001567610	FM1024 (B) WW	60	24	22-May-2014
529108	1001634260	FM1024 (B) WW	60	24	22-May-2014
529108	1001744620	FM1024 (B) WW	60	24	22-May-2014
529108	1001829580	FM1024 (B) WW	60	24	27-Aug-2014
529108	1002044710	FM1024 (B) WW	60	24	27-Aug-2014
529108	1002090510	FM1024 (B) WW	60	24	13-Nov-2014
529108	1002175950	FM1024 (B) WW	60	24	13-Nov-2014
529108	1002223920	FM1024 (B) WW	60	24	27-Feb-2015
529108	1002392160	FM1024 (B) WW	60	24	24-Apr-2015
529108	1002449900	FM1024 (B) WW	60	24	25-Jun-2015
529108	1002494590	FM1024 (B) WW	60	24	10-Jul-2015
529108	1002565460	FM1024 (B) WW	60	24	22-Jul-2015
529108	1002615530	FM1024 (B) WW	60	24	22-Aug-2015
529108	1002706050	FM1024 (B) WW	60	24	25-Sep-2015
529108	1002785800	FM1024 (B) WW	60	24	7-Nov-2015
529108	1002960400	FM1024 (B) WW	60	24	16-Jan-2016
529108	1002992240	FM1024 (B) WW	60	24	20-Feb-2016
529108	1003099530	FM1024 (B) WW	60	24	27-Mar-2016
529108	1003182230	FM1024 (B) WW	60	24	15-May-2016
529108	1003322130	FM1024 (B) WW	60	24	10-Jul-2016
529108	1003404520	FM1024 (B) WW	60	24	18-Aug-2016
529108	1003491000	FM1024 (B) WW	60	24	18-Sep-2016
529108	1003526910	FM1024 (B) WW	60	24	8-Oct-2016
529108	1003580860	FM1024 (B) WW	60	24	30-Oct-2016
529108	1003629820	FM1024 (B) WW	60	24	20-Nov-2016
529140	1001390510	FM1024 (B) US	60	24	22-Mar-2014
529140	1001441860	FM1024 (B) US	60	24	22-May-2014
529140	1001609400	FM1024 (B) US	60	24	22-May-2014
529140	1001733320	FM1024 (B) US	60	24	27-Aug-2014
529140	1001761030	FM1024 (B) US	60	24	27-Aug-2014
529140	1001920530	FM1024 (B) US	60	24	13-Nov-2014
529140	1001966610	FM1024 (B) US	60	24	13-Nov-2014
529140	1002009360	FM1024 (B) US	60	24	13-Nov-2014



529140	1002084930	FM1024 (B) US	60	24	13-Nov-2014
529140	1002106570	FM1024 (B) US	60	24	13-Nov-2014
529140	1002158050	FM1024 (B) US	60	24	27-Feb-2015
529140	1002168110	FM1024 (B) US	60	24	27-Feb-2015
529140	1002395840	FM1024 (B) US	60	24	24-Apr-2015
529140	1002452170	FM1024 (B) US	60	24	25-Jun-2015
529140	1002500020	FM1024 (B) US	60	24	10-Jul-2015
529140	1002604960	FM1024 (B) US	60	24	22-Aug-2015
529140	1002992250	FM1024 (B) US	60	24	20-Feb-2016
529140	1003030810	FM1024 (B) US	60	24	6-Mar-2016
529140	1003127520	FM1024 (B) US	60	24	17-Apr-2016
529140	1003274260	FM1024 (B) US	60	24	25-Jun-2016
529140	1003322150	FM1024 (B) US	60	24	10-Jul-2016
529140	1003412730	FM1024 (B) US	60	24	18-Aug-2016
529140	1003535930	FM1024 (B) US	60	24	18-Sep-2016
529140	1003678890	FM1024 (B) US	60	24	4-Dec-2016
529148	1001368050	FM1024 (B) US	60	24	22-Mar-2014
529148	1001442030	FM1024 (B) US	60	24	22-May-2014
529148	1001566960	FM1024 (B) US	60	24	22-May-2014
529148	1001578760	FM1024 (B) US	60	24	22-May-2014
529148	1001708630	FM1024 (B) US	60	24	22-May-2014
529148	1001833500	FM1024 (B) US	60	24	27-Aug-2014
529148	1001894590	FM1024 (B) US	60	24	27-Aug-2014
529148	1001920200	FM1024 (B) US	60	24	27-Aug-2014
529148	1001955170	FM1024 (B) US	60	24	27-Aug-2014
529148	1002084950	FM1024 (B) US	60	24	13-Nov-2014



529148	1002172820	FM1024 (B) US	60	24	13-Nov-2014
529148	1002226550	FM1024 (B) US	60	24	27-Feb-2015
529148	1002410940	FM1024 (B) US	60	24	24-Apr-2015
529148	1002451250	FM1024 (B) US	60	24	25-Jun-2015
529148	1002501640	FM1024 (B) US	60	24	10-Jul-2015
529148	1002604970	FM1024 (B) US	60	24	22-Aug-2015
529148	1002964340	FM1024 (B) US	60	24	16-Jan-2016
529148	1002992260	FM1024 (B) US	60	24	20-Feb-2016
529148	1003121770	FM1024 (B) US	60	24	17-Apr-2016
529148	1003274280	FM1024 (B) US	60	24	25-Jun-2016
529148	1003491070	FM1024 (B) US	60	24	18-Sep-2016
529148	1003526920	FM1024 (B) US	60	24	8-Oct-2016
529148	1003626710	FM1024 (B) US	60	24	20-Nov-2016

Table 2: Product with remaining shelf life

REF	Lot#	Product Name	Current Shelf Life	Corrected Shelf Life	Corrected Expiration Date
529100	1003836110	FM1024 (B) WW	60	24	29-Jan-2017
529100	1004100080	FM1024 (B) WW	60	24	3-Jun-2017
529100	1004137920	FM1024 (B) WW	60	24	16-Jun-2017
529100	1004273550	FM1024 (B) WW	60	24	19-Aug-2017
529100	1004381380	FM1024 (B) WW	60	24	15-Apr-2017
529100	1004593700	FM1024 (B) WW	60	24	2-Dec-2017
529100	1004629890	FM1024 (B) WW	60	24	9-Jan-2018
529100	1004631880	FM1024 (B) WW	60	24	9-Jan-2018
529100	1004851860	FM1024 (B) WW	60	24	14-Apr-2018
529100	1005034300	FM1024 (B) WW	60	24	29-Jun-2018
529100	1005192380	FM1024 (B) WW	60	24	15-Sep-2018
529100	1005261410	FM1024 (B) WW	60	24	6-Oct-2018
529108	1003876820	FM1024 (B) WW	60	24	19-Feb-2017
529108	1004022140	FM1024 (B) WW	60	24	28-Apr-2017
529108	1004177620	FM1024 (B) WW	60	24	1-Jul-2017
529108	1004323320	FM1024 (B) WW	60	24	2-Sep-2017



529108	1004576570	FM1024 (B) WW	60	24	16-Dec-2017
529108	1004680780	FM1024 (B) WW	60	24	3-Feb-2018
529108	1004941770	FM1024 (B) WW	60	24	2-Jun-2018
529108	1005098120	FM1024 (B) WW	60	24	11-Jul-2018
529108	1005212770	FM1024 (B) WW	60	24	22-Sep-2018
529108	1005302500	FM1024 (B) WW	60	24	13-Oct-2018
529140	1003800400	FM1024 (B) US	60	24	22-Jan-2017
529140	1004100220	FM1024 (B) US	60	24	3-Jun-2017
529140	1004177630	FM1024 (B) US	60	24	1-Jul-2017
529140	1004365540	FM1024 (B) US	60	24	4-May-2017
529140	1004410620	FM1024 (B) US	60	24	7-Oct-2017
529140	1004557900	FM1024 (B) US	60	24	9-Dec-2017
529140	1004703240	FM1024 (B) US	60	24	27-Jan-2018
529140	1004783050	FM1024 (B) US	60	24	10-Mar-2018
529140	1004838760	FM1024 (B) US	60	24	14-Apr-2018
529140	1005034320	FM1024 (B) US	60	24	29-Jun-2018
529140	1005097790	FM1024 (B) US	60	24	28-Jul-2018
529140	1005151830	FM1024 (B) US	60	24	25-Aug-2018
529148	1003743380	FM1024 (B) US	60	24	15-Jan-2017
529148	1003946090	FM1024 (B) US	60	24	1-Apr-2017
529148	1004037330	FM1024 (B) US	60	24	4-May-2017
529148	1004273540	FM1024 (B) US	60	24	19-Aug-2017
529148	1004323330	FM1024 (B) US	60	24	2-Sep-2017
529148	1004557890	FM1024 (B) US	60	24	9-Dec-2017
529148	1004593710	FM1024 (B) US	60	24	2-Dec-2017
529148	1004696420	FM1024 (B) US	60	24	27-Jan-2018
529148	1004790240	FM1024 (B) US	60	24	24-Mar-2018
529148	1005031600	FM1024 (B) US	60	24	16-Jun-2018
529148	1005098130	FM1024 (B) US	60	24	11-Jul-2018
529148	1005151890	FM1024 (B) US	60	24	1-Sep-2018
529148	1005151920	FM1024 (B) US	60	24	25-Aug-2018





Attachment A: Acknowledgement Form- FSCA 3193

**In order to Comply with Competent Authority Regulations please
complete and return this Acknowledgement Form**

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

I acknowledge the receipt of bioMérieux Urgent Field Safety Notice informing this laboratory on the ETEST® Fosfomicin FM1024 (Ref. 529140, 529148, 529100, 529108) 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:

Date:

Signature:

