Attachment 1

URGENT FIELD SAFETY NOTICE
FSCA3193

DECEMBER 15, 2016

ETEST® Ceftazidime TZ256 (Ref. 506758, 506718) Foam packaging

Dear Laboratory Manager or Laboratory Director,

Our records indicate that your laboratory received the following products. This letter is intended for all ETEST® Ceftazidime TZ256 (Ref. 506758, 506718) Foam packaging US & World Wide users. Product reference and lot numbers are indicated on 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® Ceftazidime TZ256 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 twelve (12) months.
When used within the revised shelf-life, the product will continue to perform per its labeled performance specifications. The following issue has been identified:

⇨ QC failure (MICs above the upper QC limit) for some Quality Control strains listed in the Instructions For Use on ETEST® Ceftazidime TZ256 (Ref. 506758, 506718) Foam packaging after 12 months of shelf-life.

Impact to Patient/User:

As a result of the observed performance issue, there is a potential to obtain an MIC result that is higher than expected after 12 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® Ceftazidime TZ256 (Ref. 506758, 506718), Foam packaging** (lots listed in Table 1) which are now designated as expired.
- Immediately order the replacement products appropriate for your institution.
- Laboratories should continue to follow their current QC procedures for **ETEST® Ceftazidime TZ256 (Ref. 506758, 506718)** 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 organism defined as the stability indicator for ETEST® Ceftazidime TZ256 (Ref. 506758, 506718) that is *E.coli* ATCC25922 strain (Expected range- MIC: 0,064-0.5 µg/mL). The MIC result for this specific strain must fall in the acceptable range to confirm the validity of the QC test and performance of the ETEST strip.

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- When replacement product is received, discontinue using and discard impacted **ETEST® Ceftazidime TZ256 (Ref. 506758, 506718)** lots listed in Table 1.

Product with remaining shelf life:

- The remaining products in Table 2, may be used within the revised shelf life requirements as defined in Table 2 below.
- Correct 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.

- Contact your local bioMérieux representative for product compensation.

    - Please note, **ETEST® Ceftazidime TZ256 (Ref. 412293, 412292) SPB** packaging performs within the specifications until its labeled expiration date.

- 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 Clinical Customer Service representative

Sincerely,

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
506718	1003788640	**TZ256 (F)** WW	24	12	11-Feb-2016
506718	1003823960	**TZ256 (F)** WW	24	12	19-Mar-2016
506718	1003945320	**TZ256 (F)** WW	24	12	16-Apr-2016
506718	1004427210	**TZ256 (F)** WW	24	12	3-Nov-2016
506718	1004510360	**TZ256 (F)** WW	24	12	8-Dec-2016
506758	1003693010	**TZ256 (F)** US	24	12	7-Jan-2016
506758	1003922720	**TZ256 (F)** US	24	12	7-Apr-2016
506758	1003945330	**TZ256 (F)** US	24	12	16-Apr-2016
506758	1004193850	**TZ256 (F)** US	24	12	29-Jul-2016
506758	1004325620	**TZ256 (F)** US	24	12	24-Sep-2016
506758	1004427220	**TZ256 (F)** US	24	12	3-Nov-2016
506758	1004510540	**TZ256 (F)** US	24	12	8-Dec-2016

Table 2: Product with remaining shelf life.

REF	Lot #	Product Name	Current Shelf Life	Corrected Shelf Life	Corrected Expiration Date
506718	1004719300	**TZ256 (F)** WW	24	12	10-Mar-2017
506718	1004830170	**TZ256 (F)** WW	24	12	27-Apr-2017
506758	1004720640	**TZ256 (F)** US	24	12	10-Mar-2017
506758	1004830190	**TZ256 (F)** US	24	12	27-Apr-2017

Attachment A: Acknowledgement Form.

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® Ceftazidime TZ256 (Ref. 506758, 506718) 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 : ……..**

Attachment 2

URGENT FIELD SAFETY NOTICE
FSCA3193

DECEMBER 15, 2016

ETEST® Cephalotin CE 256 (Ref. 503558, 503518) FOAM packaging

Dear Laboratory Manager or Laboratory Director,

Our records indicate that your laboratory received the following products. This letter is intended for all ETEST® Cephalotin CE 256 (Ref. 503558, 503518) FOAM packaging US & World Wide users. The product reference and lot numbers are included in Table 1.

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® Cephalotin CE 256 product listed in Table 1 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 twelve (12) 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® Cephalotin CE 256 (Ref. 503558, 503518) FOAM packaging starting after 12 months of shelf-life

Impact to Patient/User:

As a result of the observed performance issue, there is a potential to obtain a MIC result that is higher than expected after 12 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® Cephalotin CE 256 (Ref. 503558, 503518) Foam** packaging which are now expired. These lots are in Table 1 below.
- Immediately order the replacement products appropriate for your institution.
- Laboratories should continue to follow their current QC procedures for **ETEST® Cephalotin CE 256 (Ref. 503558, 503518)** 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 organism defined as the stability indicator for ETEST® Cephalotin CE 256 (Ref. 503558, 503518) that is *E.coli* ATCC25922 strain (Expected range- MIC: 4-16 µg/mL). The MIC result for this specific strain must fall in the acceptable range to confirm the validity of the QC test and performance of the ETEST strip.
- The customer letter will also advise them to work within their own internal processes to determine if any retrospective analysis is needed.

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- Only report patient results if the QC is in the acceptable range.

- When you have received replacement product, discontinue using and discard impacted lots of **ETEST® Cephalotin CE 256 (Ref. 503558, 503518) Foam** packaging, lots listed in Table 1.

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.
- Contact your local bioMérieux representative for product compensation.

  - Please note, **ETEST® Cephalotin CE 256 (Ref. 412306, 412307) SPB** packaging performs within the specifications until the labeled expiration date.

- 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 Clinical Customer Service representative

Sincerely,

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
503518	1003161140	CE 256 (F) WW	36	12	20-May-2015
503558	1003158260	CE 256 (F) US	36	12	20-May-2015

Attachment A: Acknowledgement Form.

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® Cephalotin CE 256 (Ref. 503558, 503518) 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

Attachment 3

URGENT FIELD SAFETY NOTICE
FSCA3193

DECEMBER 15, 2016

Etest® Ceftriaxone TXL32 (Ref. 412302, 412303) SPB Packaging

Dear Laboratory Manager or Laboratory Director,

This letter is intended for all **ETEST® Ceftriaxone TXL32 (**Ref. 412302, 412303) SPB packaging US & World Wide users. Our records indicate that your laboratory received the following products (reference and lot numbers are included in Table 1 and Table 2).

As a part of our ongoing thorough analysis of the ETEST® product range, we have observed internally two issues with ETEST® Ceftriaxone TXL32 (Ref. 412302, 412303) SPB that may affect the test performance.

Issue 1: Description: Stability issue
We have observed internally that the current shelf-life claims of the ETEST® Ceftriaxone TXL32 products listed in Table 1 and Table 2 are not supported by internal testing. As a result there is a potential for an overestimation of the MIC values for specifically *Neisseria gonorrhoeae*. No increase of the complaint trend was observed for these products, but we are taking the precaution of revising the shelf-life claims.

The following was identified:
QC failure (MICs above the upper QC limit) for Quality Control strain *N. gonorrhoeae* ATCC 49226 listed in the Instructions For Use on the ETEST® Ceftriaxone TXL32 (Ref. 412302, 412303) SPB packaging after 12 months of shelf-life.

Impact to Patient/User:
There is a potential to obtain a MIC result that is higher than expected after 12 months of product shelf-life. This type of error would be detectable during quality control testing as an out of range MIC result would be obtained for the QC strain. Patient results may also be elevated resulting in a false non-susceptible or a false resistant result.

Required actions:
The following recommendations require your immediate attention to ensure the product will continue to perform per its labeled performance specifications, within its revised shelf-life of twelve (12) months.

- Identify impacted lots of **ETEST® Ceftriaxone TXL32 (Ref. 412302, 412303)** (lots listed in Table 1 below) which are now expired after shelf-life reduction.
- Immediately order the replacement products appropriate for your institution.
- Until replacement product is available Laboratories may continue to use their now expired strips with the following recommendations:
    - Laboratories should continue to follow their current QC procedures for **ETEST® Ceftriaxone TXL32 (Ref. 412302, 412303)** for the lots listed in Table 1 in accordance with CLIA and local regulatory requirements, with a modification to increase the

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frequency of QC testing to weekly or every day of use if previous QC testing exceeds one week.

- Laboratories should include in the QC testing the strain *N. gonorrhoeae* ATCC 49226 (Expected range-MIC: 0,004-0,016 µg/mL) defined as the stability indicator for ETEST® Ceftriaxone TXL32 (Ref. 412302, 412303). The MIC result for this specific strain must fall in the acceptable range to confirm the validity of the QC test and performance of the ETEST with the clinical isolate.
- Only report results if all QC is in the acceptable ranges.

- When replacement product is received, discontinue using and discard impacted **ETEST® Ceftriaxone TXL32 (Ref. 412302, 412303)** (listed in Table 1).

Issue 2: Description: A potential performance issue on strain categorization

The following was identified:

- For *Streptococcus pneumoniae* meningitis strains: based on 2016 **CLSI** guidelines a reduced MIC value might be obtained with ETEST® TXL32 (SPB and FOAM packaging) that could lead to a susceptible categorization instead of intermediate categorization (Minor Error) or resistant categorization (Very Major Error) for clinical strains as compared to broth microdulution (BMD) reference method.

- For *Streptococcus pneumoniae* strains (meningitis and non-meningitis): based on 2016 **EUCAST** guidelines a reduced MIC value could be obtained with ETEST® TXL32 SBP and FOAM packaging) leading to a susceptible categorization instead of intermediate categorization for clinical strains as compared to BMD reference method: Minor error.

Impact to Patient/User:

There is a potential to obtain:

- A susceptible result instead of an intermediate result (Minor Error) or resistant result (Very Major Error) for *Streptococcus pneumoniae* meningitis strains with ETEST® TXL32 SPB and FOAM packaging compared to the BMD reference method using 2016 **CLSI** guidelines.
- A susceptible result instead of an intermediate result (Minor Error) for *Streptococcus pneumoniae* strains with ETEST® TXL32 SPB and FOAM packaging compared to the BMD reference method and based on 2016 **EUCAST** guidelines.

Recommendations for users under CLSI guidelines: To inform customer that there is a potential to obtain a false susceptible result instead of intermediate or resistant result compared to the BMD reference method for *Streptococcus pneumoniae* meningitis based on 2016 CLSI breakpoints with ETEST® TXL32 (FOAM and SPB packaging). Laboratories can continue to use ETEST® TXL32 for *Streptococcus pneumoniae* meningitis when applying the following recommendations:

- **Under the following conditions ETEST® TXL32 results can be directly reported for *Streptococcus pneumoniae* (CLSI meningitis):**
  - Isolate tests penicillin susceptible (MIC ≤0.06 µg/ml) and ceftriaxone susceptible (**ETEST® TXL32** MIC ≤0.5 µg/ml)
  - Isolate tests penicillin resistant (MIC ≥0.12 µg/ml) and ceftriaxone resistant (**ETEST® TXL32** ≥ 2 µg/ml)

- **For isolates testing penicillin resistant (MIC ≥0.12 µg/ml) and ceftriaxone susceptible (ETEST® TXL32 MIC ≤0.5 µg/ml) or intermediate (ETEST® TXL32 MIC=1 µg/ml), the ceftriaxone MIC should be confirmed using an alternative MIC test method.**

Recommendations for users under EUCAST guidelines: to inform the customer that there is a potential to obtain a false susceptible result instead of intermediate result for *Streptococcus pneumoniae* strains compared to the BMD reference method based on 2016 **EUCAST** guidelines for ETEST® TXL32 (FOAM and SPB packaging). Laboratories can continue to use ETEST® TXL32 for *Streptococcus pneumoniae* when applying the following the recommendations:

- Laboratories should verify the result by an alternative method for each *Streptococcus pneumoniae* isolate (meningitis and non-meningitis) with an **ETEST® TXL32** MIC ≥0.5 μg/ml). This verification **is not needed** for isolates that are known to be fully susceptible to benzylpenicillin (MIC ≤0.06 μg/ml) or that have an oxacillin zone diameter >8 mm.

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.

- Alternative methods of testing for Ceftriaxone and Streptococcus pneumonia are available, please contact bioMérieux for automated alternate methods.

- 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 Clinical Customer Service representative

Sincerely,

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
412302	1002939460	TX 32 SPB US	36	12	10-Feb-2015
412302	1003361690	TX 32 SPB US	36	12	18-Aug-2015
412302	1003848910	TX 32 SPB US	36	12	9-Mar-2016
412302	1004041770	TX 32 SPB US	36	12	28-May-2016
412302	1004394530	TX 32 SPB US	36	12	21-Oct-2016
412303	1002939450	TX 32 SPB WW	36	12	10-Feb-2015
412303	1003089900	TX 32 SPB WW	36	12	15-Apr-2015
412303	1003813690	TX 32 SPB WW	36	12	23-Feb-2016
412303	1003851120	TX 32 SPB WW	36	12	10-Mar-2016
412303	1003953500	TX 32 SPB WW	36	12	20-Apr-2016
412303	1004152070	TX 32 SPB WW	36	12	9-Jul-2016
412303	1004315690	TX 32 SPB WW	36	12	21-Sep-2016
412303	1004394520	TX 32 SPB WW	36	12	21-Oct-2016
412303	1004525320	TX 32 SPB WW	36	12	14-Dec-2016

Table 2: Product with remaining shelf life.

REF	Lot #	Product Name	Current Shelf-life	Corrected Shelf-life	Corrected Expiration date
412302	1004731200	TX 32 SPB US	36	12	25-Mar-2017
412302	1004876830	TX 32 SPB US	36	12	18-May-2017
412303	1002939450	TX 32 SPB WW	36	12	10-Feb-2015
412303	1003089900	TX 32 SPB WW	36	12	15-Apr-2015
412303	1004755940	TX 32 SPB WW	36	12	25-Mar-2017
412303	1004828440	TX 32 SPB WW	36	12	26-Apr-2017
412303	1004876840	TX 32 SPB WW	36	12	18-May-2017
412303	1005118100	TX 32 SPB WW	36	12	30-Aug-2017

Attachment A: Acknowledgement Form.

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® Ceftriaxone TXL32 (Ref. 412302, 41303) 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

Attachment 4

URGENT FIELD SAFETY NOTICE
FSCA3193

DECEMBER, 15, 2016

ETEST® Ciprofloxacin CI 32 (Ref. 508650, 508658, 508610, 508618) FOAM packaging

Dear Laboratory Manager or Laboratory Director,

Our records indicate that your laboratory received the following products. This letter is intended for all ETEST® Ciprofloxacin CI 32 (Ref. 508650, 508658, 508610, 508618) FOAM packaging US & World Wide users. Product reference and lot numbers are included 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® Ciprofloxacin CI 32 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 twelve (12) months.

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

⇨ QC failure (MICs above the upper QC limit): for some Quality Control strains listed in the Instructions For Use on ETEST® Ciprofloxacin CI 32 (Ref. 508650, 508658, 508610, 508618) FOAM packaging starting after 12 months of shelf-life.

Impact to Patient/User:

As a result of the observed performance issue, there is a potential to obtain a MIC result that is higher than expected after 12 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® Ciprofloxacin CI 32 (Ref. 508650, 508658, 508610, 508618) FOAM** packaging (lots listed Table 1 below) which are now designated as expired.
- Immediately order the replacement products appropriate for your institution.
- Laboratories should continue to follow their current QC procedures for **ETEST® Ciprofloxacin CI 32 (Ref. 508650, 508658, 508610, 508618)**, 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 organism defined as the stability indicator for ETEST® Ciprofloxacin CI 32 (Ref. 508650, 508658, 508610, 508618) that is *E.coli* ATCC25922 strain (Expected range-MIC: 0,004-0,016 µg/mL). The MIC result for this specific strain must fall in the acceptable range to confirm the validity of the QC test and performance of the Etest strip.

- When replacement product is received, discontinue using and discard **ETEST® Ciprofloxacin CI 32 (Ref. 508650, 508658, 508610, 508618)**, lots listed in Table 1.

Product with remaining shelf life:

- Identify products in **Table 2.** These products may be used within the revised shelf life requirements defined within Table 2.
- Correct 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.

- Contact your local bioMérieux representative for product compensation.

    - Please note, **ETEST® Ciprofloxacin CI32 (Ref. 412310, 412311) SPB** packaging performs within the specifications until the labeled expiration date.

- 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 Clinical Customer Service representative

Sincerely,

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
508610	1001026950	**CI 32 (F)** WW	60	12	7-Jan-2013
508610	1001199360	**CI 32 (F)** WW	60	12	7-Jan-2013
508610	1001427690	**CI 32 (F)** WW	60	12	15-May-2013
508610	1001518090	**CI 32 (F)** WW	60	12	15-May-2013
508610	1001595490	**CI 32 (F)** WW	60	12	30-Jul-2013
508610	1001740320	**CI 32 (F)** WW	60	12	30-Jul-2013
508610	1001989260	**CI 32 (F)** WW	60	12	10-Dec-2013
508618	1001032350	**CI 32 (F)** WW	60	12	7-Jan-2013
508618	1001242030	**CI 32 (F)** WW	60	12	7-Jan-2013
508618	1001338050	**CI 32 (F)** WW	60	12	7-Jan-2013
508618	1001416820	**CI 32 (F)** WW	60	12	7-Jan-2013
508618	1001471720	**CI 32 (F)** WW	60	12	15-May-2013
508618	1001595500	**CI 32 (F)** WW	60	12	15-May-2013
508618	1001627650	**CI 32 (F)** WW	60	12	15-May-2013
508618	1001720440	**CI 32 (F)** WW	60	12	15-May-2013
508618	1001728140	**CI 32 (F)** WW	60	12	30-Jul-2013
508618	1001786480	**CI 32 (F)** WW	60	12	30-Jul-2013
508618	1001956220	**CI 32 (F)** WW	60	12	10-Dec-2013
508618	1002109250	**CI 32 (F)** WW	60	12	28-Jan-2014
508618	1002338880	**CI 32 (F)** WW	60	12	23-May-2014
508618	1002435190	**CI 32 (F)** WW	60	12	26-Jun-2014
508618	1002566960	**CI 32 (F)** WW	60	12	26-Aug-2014
508618	1002718380	**CI 32 (F)** WW	60	12	30-Oct-2014
508618	1002975330	**CI 32 (F)** WW	60	12	25-Feb-2015
508618	1003886270	**CI 32 (F)** WW	60	12	23-Mar-2016
508618	1003894060	**CI 32 (F)** WW	60	12	25-Mar-2016
508618	1003981160	**CI 32 (F)** WW	60	12	2-May-2016
508618	1004064990	**CI 32 (F)** WW	60	12	6-Jun-2016
508618	1004075190	**CI 32 (F)** WW	60	12	9-Jun-2016
508618	1004168390	**CI 32 (F)** WW	60	12	18-Jul-2016
508618	1004490810	**CI 32 (F)** WW	60	12	29-Nov-2016
508650	1001060450	**CI 32 (F)** US	60	12	7-Jan-2013
508650	1001154650	**CI 32 (F)** US	60	12	7-Jan-2013
508650	1001212890	**CI 32 (F)** US	60	12	7-Jan-2013
508650	1001264540	**CI 32 (F)** US	60	12	7-Jan-2013
508650	1001319180	**CI 32 (F)** US	60	12	7-Jan-2013
508650	1001390080	**CI 32 (F)** US	60	12	7-Jan-2013
508650	1001390440	**CI 32 (F)** US	60	12	15-May-2013
508650	1001409510	**CI 32 (F)** US	60	12	15-May-2013
508650	1001409520	**CI 32 (F)** US	60	12	15-May-2013
508650	1001441760	**CI 32 (F)** US	60	12	15-May-2013
508650	1001540660	**CI 32 (F)** US	60	12	30-Jul-2013
508650	1001589490	**CI 32 (F)** US	60	12	30-Jul-2013

508650	1001621240	**CI 32 (F)** US	60	12	30-Jul-2013
508650	1001656460	**CI 32 (F)** US	60	12	30-Jul-2013
508658	1001093880	**CI 32 (F)** US	60	12	7-Jan-2013
508658	1001154820	**CI 32 (F)** US	60	12	7-Jan-2013
508658	1001265110	**CI 32 (F)** US	60	12	7-Jan-2013
508658	1001319480	**CI 32 (F)** US	60	12	7-Jan-2013
508658	1001390570	**CI 32 (F)** US	60	12	7-Jan-2013
508658	1001441910	**CI 32 (F)** US	60	12	15-May-2013
508658	1001487610	**CI 32 (F)** US	60	12	15-May-2013
508658	1001647880	**CI 32 (F)** US	60	12	15-May-2013
508658	1001708510	**CI 32 (F)** US	60	12	15-May-2013
508658	1001811360	**CI 32 (F)** US	60	12	30-Jul-2013
508658	1002041010	**CI 32 (F)** US	60	12	10-Dec-2013
508658	1002102920	**CI 32 (F)** US	60	12	10-Dec-2013
508658	1002435570	**CI 32 (F)** US	60	12	26-Jun-2014
508658	1002567240	**CI 32 (F)** US	60	12	26-Aug-2014
508658	1002725010	**CI 32 (F)** US	60	12	3-Nov-2014
508658	1003246020	**CI 32 (F)** US	60	12	30-Jun-2015
508658	1003889730	**CI 32 (F)** US	60	12	24-Mar-2016
508658	1004168400	**CI 32 (F)** US	60	12	18-Jul-2016
508658	1004364330	**CI 32 (F)** US	60	12	10-Oct-2016
508658	1004491220	**CI 32 (F)** US	60	12	29-Nov-2016

Table 2: Product with remaining shelf life

REF	Lot#	Product Name	Current Shelf Life	Corrected Shelf Life	Corrected Expiration Date
508618	1004939640	**CI 32 (F)** WW	60	12	9-Jun-2017
508658	1004939670	**CI 32 (F)** US	60	12	9-Jun-2017

Attachment A: Acknowledgement Form.

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® Ciprofloxacin CI 32 (Ref. 508650, 508658, 508610, 508618) 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

Attachment 5

URGENT FIELD SAFETY NOTICE
FSCA3193

DECEMBER 15, 2016

ETEST® Vancomycin VA 256 (Ref. 525550, 525558, 525510, 525518) FOAM packaging

Dear Laboratory Manager or Laboratory Director,

Our records indicate that your laboratory received the following products. This letter is intended for all ETEST® Vancomycin VA 256 (Ref. 525550, 525558, 525510, 525518) FOAM 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® Vancomycin VA 256 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 twelve (12) 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® Vancomycin VA 256 (Ref. 525550, 525558, 525510, 525518) FOAM packaging over the product shelf-life starting after 12 months of shelf-life.

Impact to Patient/User:

As a result of the observed performance issue, there is a potential to obtain a MIC result that is higher than expected after 12 months. 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® Vancomycin VA 256 (Ref. 525550, 525558, 525510, 525518) FOAM** 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® Vancomycin VA 256 (Ref. 525550, 525558, 525510, 525518)** 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 organism defined as the stability indicator for ETEST® Vancomycin VA 256 (Ref. 525550, 525558, 525510, 525518) that are *E. faecalis* ATCC 29212 (Expected range-MIC: 1-4 µg/ml) and *S.pneumoniae* ATCC 49619 (Expected range-MIC: 0.125-0.5 µg/ml). The MIC result for those specific strains must fall in the acceptable range to confirm the validity of the QC test and performance of the ETEST strip.

bioMérieux, Inc.
100 Rodolphe Street, Durham, NC 27712
Phone: (800) 634-7656- www.biomerieux-usa.com

- When replacement product is received, discontinue using and discard impacted **ETEST® Vancomycin VA 256 (Ref. 525550, 525558, 525510, 525518)** lots listed in Table 1.

Product with remaining shelf life:

- Identify products in Table 2. These products may be used within the revised shelf life requirements as defined in Table 2.
- Correct 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.
    - Please note, **ETEST® (Vancomycin) SPB packaging (Ref. 412486, 412488) SPB packaging** performs within the specifications until the labeled expiration date.
- 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 Clinical Customer Service representative.

Sincerely,

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
525510	1001051200	VA 256 (F) WW	60	12	28-Jan-2013
525510	1001125840	VA 256 (F) WW	60	12	4-Mar-2013
525510	1001416930	VA 256 (F) WW	60	12	4-Mar-2013
525510	1001455150	VA 256 (F) WW	60	12	4-Mar-2013
525510	1001548250	VA 256 (F) WW	60	12	26-Jun-2013
525510	1001596090	VA 256 (F) WW	60	12	26-Jun-2013
525518	1001192860	VA 256 (F) WW	60	12	28-Jan-2013
525518	1001223460	VA 256 (F) WW	60	12	28-Jan-2013
525518	1001317000	VA 256 (F) WW	60	12	28-Jan-2013
525518	1001338170	VA 256 (F) WW	60	12	4-Mar-2013
525518	1001416940	VA 256 (F) WW	60	12	4-Mar-2013
525518	1001416950	VA 256 (F) WW	60	12	15-Apr-2013
525518	1001492590	VA 256 (F) WW	60	12	29-May-2013
525518	1001566860	VA 256 (F) WW	60	12	29-May-2013
525518	1001634070	VA 256 (F) WW	60	12	26-Jun-2013
525518	1001728340	VA 256 (F) WW	60	12	26-Jun-2013
525518	1001761460	VA 256 (F) WW	60	12	16-Sep-2013
525518	1001887350	VA 256 (F) WW	60	12	18-Nov-2013
525518	1001894800	VA 256 (F) WW	60	12	22-Nov-2013
525518	1002007990	VA 256 (F) WW	60	12	9-Jan-2014
525518	1002045080	VA 256 (F) WW	60	12	23-Jan-2014
525518	1002113290	VA 256 (F) WW	60	12	17-Feb-2014
525518	1002197250	VA 256 (F) WW	60	12	20-Mar-2014
525518	1002287970	VA 256 (F) WW	60	12	29-Apr-2014
525518	1002338070	VA 256 (F) WW	60	12	22-May-2014
525518	1002369060	VA 256 (F) WW	60	12	2-Jun-2014
525518	1002440920	VA 256 (F) WW	60	12	30-Jun-2014
525518	1002463490	VA 256 (F) WW	60	12	8-Jul-2014
525518	1002496690	VA 256 (F) WW	60	12	21-Jul-2014
525518	1002565090	VA 256 (F) WW	60	12	25-Aug-2014
525518	1002583690	VA 256 (F) WW	60	12	2-Sep-2014
525518	1002604690	VA 256 (F) WW	60	12	11-Sep-2014
525518	1002663860	VA 256 (F) WW	60	12	8-Oct-2014
525518	1002809200	VA 256 (F) WW	60	12	8-Dec-2014
525518	1002809880	VA 256 (F) WW	60	12	9-Dec-2014
525518	1002876470	VA 256 (F) WW	60	12	13-Jan-2015
525518	1002922750	VA 256 (F) WW	60	12	3-Feb-2015
525518	1003079740	VA 256 (F) WW	60	12	10-Apr-2015
525518	1003134480	VA 256 (F) WW	60	12	11-May-2015
525518	1003373510	VA 256 (F) WW	60	12	24-Aug-2015
525518	1003621540	VA 256 (F) WW	60	12	3-Dec-2015

525518	1003778630	VA 256 (F) WW	60	12	9-Feb-2016
525518	1003809630	VA 256 (F) WW	60	12	19-Feb-2016
525518	1003910700	VA 256 (F) WW	60	12	1-Apr-2016
525518	1003972790	VA 256 (F) WW	60	12	27-Apr-2016
525518	1004052410	VA 256 (F) WW	60	12	1-Jun-2016
525518	1004121860	VA 256 (F) WW	60	12	28-Jun-2016
525518	1004150380	VA 256 (F) WW	60	12	8-Jul-2016
525518	1004256770	VA 256 (F) WW	60	12	25-Aug-2016
525518	1004371490	VA 256 (F) WW	60	12	12-Oct-2016
525518	1004496990	VA 256 (F) WW	60	12	30-Nov-2016
525518	1004508060	VA 256 (F) WW	60	12	6-Dec-2016
525550	1001094650	VA 256 (F) US	60	12	28-Jan-2013
525550	1001136230	VA 256 (F) US	60	12	4-Mar-2013
525550	1001212920	VA 256 (F) US	60	12	4-Mar-2013
525550	1001293800	VA 256 (F) US	60	12	4-Mar-2013
525550	1001302920	VA 256 (F) US	60	12	4-Mar-2013
525550	1001319720	VA 256 (F) US	60	12	4-Mar-2013
525550	1001334090	VA 256 (F) US	60	12	4-Mar-2013
525550	1001391310	VA 256 (F) US	60	12	4-Mar-2013
525550	1001430030	VA 256 (F) US	60	12	4-Mar-2013
525550	1001518060	VA 256 (F) US	60	12	26-Jun-2013
525550	1001686190	VA 256 (F) US	60	12	26-Jun-2013
525558	1001174720	VA 256 (F) US	60	12	28-Jan-2013
525558	1001251340	VA 256 (F) US	60	12	4-Mar-2013
525558	1001334100	VA 256 (F) US	60	12	15-Apr-2013
525558	1001368020	VA 256 (F) US	60	12	15-Apr-2013
525558	1001442000	VA 256 (F) US	60	12	29-May-2013
525558	1001566840	VA 256 (F) US	60	12	26-Jun-2013
525558	1001647970	VA 256 (F) US	60	12	15-Jul-2013
525558	1001734920	VA 256 (F) US	60	12	15-Jul-2013
525558	1001761450	VA 256 (F) US	60	12	15-Jul-2013
525558	1001761480	VA 256 (F) US	60	12	16-Sep-2013
525558	1001897000	VA 256 (F) US	60	12	18-Nov-2013
525558	1001898600	VA 256 (F) US	60	12	22-Nov-2013
525558	1002008040	VA 256 (F) US	60	12	9-Jan-2014
525558	1002073480	VA 256 (F) US	60	12	23-Jan-2014
525558	1002197270	VA 256 (F) US	60	12	21-Mar-2014
525558	1002282890	VA 256 (F) US	60	12	28-Apr-2014
525558	1002338820	VA 256 (F) US	60	12	22-May-2014
525558	1002365880	VA 256 (F) US	60	12	2-Jun-2014
525558	1002443950	VA 256 (F) US	60	12	30-Jun-2014
525558	1002465840	VA 256 (F) US	60	12	8-Jul-2014
525558	1002558040	VA 256 (F) US	60	12	21-Aug-2014
525558	1002562240	VA 256 (F) US	60	12	25-Aug-2014
525558	1002733640	VA 256 (F) US	60	12	6-Nov-2014

525558	1002751340	VA 256 (F) US	60	12	14-Nov-2014
525558	1003171920	VA 256 (F) US	60	12	26-May-2015
525558	1003449250	VA 256 (F) US	60	12	22-Sep-2015
525558	1003679000	VA 256 (F) US	60	12	29-Dec-2015
525558	1003836080	VA 256 (F) US	60	12	3-Mar-2016
525558	1004040220	VA 256 (F) US	60	12	26-May-2016
525558	1004121870	VA 256 (F) US	60	12	28-Jun-2016
525558	1004151340	VA 256 (F) US	60	12	8-Jul-2016
525558	1004173130	VA 256 (F) US	60	12	19-Jul-2016
525558	1004256780	VA 256 (F) US	60	12	25-Aug-2016
525558	1004264340	VA 256 (F) US	60	12	30-Aug-2016
525558	1004371500	VA 256 (F) US	60	12	12-Oct-2016
525558	1004491190	VA 256 (F) US	60	12	30-Nov-2016
525558	1004509340	VA 256 (F) US	60	12	6-Dec-2016

Table 2: Product with remaining shelf life.

REF	Lot #	Product Name	Current Shelf Life	Corrected Shelf Life	Corrected Expiration Date
525518	1004564470	VA 256 (F) WW	60	12	4-Jan-2017
525518	1004775890	VA 256 (F) WW	60	12	4-Apr-2017
525518	1004913990	VA 256 (F) WW	60	12	1-Jun-2017
525518	1004980270	VA 256 (F) WW	60	12	27-Jun-2017
525518	1005027170	VA 256 (F) WW	60	12	18-Jul-2017
525518	1005132320	VA 256 (F) WW	60	12	4-Sep-2017
525518	1005186480	VA 256 (F) WW	60	12	26-Sep-2017
525558	1004735790	VA 256 (F) US	60	12	16-Mar-2017
525558	1004767430	VA 256 (F) US	60	12	30-Mar-2017
525558	1004775900	VA 256 (F) US	60	12	4-Apr-2017
525558	1004914010	VA 256 (F) US	60	12	1-Jun-2017
525558	1004980280	VA 256 (F) US	60	12	27-Jun-2017
525558	1005027180	VA 256 (F) US	60	12	18-Jul-2017
525558	1005132340	VA 256 (F) US	60	12	4-Sep-2017

Attachment A: Acknowledgement Form.

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® Vancomycin VA 256 (Ref. 525550, 525558, 525510, 525518) 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

Attachment 6

URGENT FIELD SAFETY NOTICE
FSCA3193

DECEMBER 15, 2016

ETEST® Doripenem DOR32 (Ref. 535958, 535918)

Dear Laboratory Manager or Laboratory Director,

Our records indicate that your laboratory received the following products. This letter is intended for all ETEST® Doripenem DOR32 (Ref. 535958, 535918) FOAM packaging US & World Wide users. Product reference and lot numbers are included 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® Doripenem DOR32 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 twelve (12) 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® Doripenem DOR32 (Ref. 535958, 535918) FOAM packaging starting after 12 months of shelf-life

Impact to Patient/User:
As a result of the observed performance issue, there is a potential to obtain a MIC result that is higher than expected after 12 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® Doripenem DOR32 (Ref. 535958, 535918) FOAM 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® Doripenem DOR32 (Ref. 535958, 535918), 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 organism defined as the stability indicator for ETEST® Doripenem DOR32 (Ref. 535958, 535918) that is *E.coli* ATCC 25922 (Expected range-MIC: 0.008-0.064 µg/mL). The MIC result for this specific strain must fall in the acceptable range to confirm the validity of the QC test and performance of the ETEST strip.

- When replacement product is received, discontinue using and discard **ETEST® Doripenem DOR32 (Ref. 535958, 535918**), lots listed in Table 1.

Product with remaining shelf life:

- Identify products in **Table 2.** These products may be used within the revised shelf life requirements defined within Table 2.
- Correct 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.

- Contact your local bioMérieux representative for product compensation.

    - Please note, **ETEST® Doripenem DOR32 (Ref. 412325, 412326) SPB packaging** performs within the specifications until the labeled expiration date.

- 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 Clinical Customer Service representative

Sincerely,

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
535918	1003902400	DOR 32 (F) WW	24	12	30-Mar-2016
535918	1004103780	DOR 32 (F) WW	24	12	22-Jun-2016
535918	1004266960	DOR 32 (F) WW	24	12	31-Aug-2016
535958	1004265390	DOR 32 (F) US	24	12	31-Aug-2016

Table 2: Product with remaining shelf life

REF	Lot#	Product Name	Current Shelf life	Corrected Shelf life	Corrected Expiration Date
535918	1004867770	DOR 32 (F) WW	24	12	13-May-2017
535958	1005138210	DOR 32 (F) US	24	12	7-Sep-2017

Attachment A: Acknowledgement Form.

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® Doripenem DOR32 (Ref. 535958, 535918) 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

Attachment 7

URGENT FIELD SAFETY NOTICE
FSCA3193

DECEMBER 15, 2016

ETEST® Benzyl Penicillin PG256 (Ref. 502558, 502518) Foam packaging

Dear Laboratory Manager or Laboratory Director,

Our records indicate that your laboratory received the following products. This letter is intended for all ETEST® Benzyl Penicillin PG256 (Ref. 502558, 502518) FOAM packaging US & World Wide users. Product reference and lot numbers are included 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® Benzyl Penicillin PG256 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 twelve (12) 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® Benzyl Penicillin PG256 (Ref. 502558, 502518) FOAM packaging starting after 12 months of shelf-life

Impact to Patient/User:

As a result of the observed performance issue, there is a potential to obtain a MIC result that is higher than expected after 12 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® Benzyl Penicillin PG256 (Ref. 502558, 502518)** (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® Benzyl Penicillin PG256 (Ref. 502558, 502518) 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 organism defined as the stability indicator for ETEST® Benzyl Penicillin PG256 (Ref. 502550, 502558, 502510, 502518) that is *B.fragilis* ATCC 25285 (Expected range-MIC: 8-32 µg/mL).

The MIC result for this specific strain must fall in the acceptable range to confirm the validity of the QC test and performance of the ETEST strip.

- When replacement product is received, discontinue using and discard **ETEST® Benzyl Penicillin PG256 (Ref. 502558, 502518),** lots listed in Table 1.

Product with remaining shelf life:

- Identify products in **Table 2.** These products may be used within the revised shelf life requirements defined within Table 2.
- Correct 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.

- Contact your local bioMérieux representative for product compensation.

    - Please note, **ETEST® PG256 (Ref. 412262, 412263) SPB packaging** performs within the specifications until the labeled expiration date.

- 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 Clinical Customer Service representative

Sincerely,

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
502518	1002911350	**PG256 (F) WW**	36	12	28-Jan-2015
502518	1002964350	**PG256 (F) WW**	36	12	20-Feb-2015
502518	1003012790	**PG256 (F) WW**	36	12	13-Mar-2015
502518	1004047370	**PG256 (F) WW**	36	12	31-May-2016
502518	1004140000	**PG256 (F) WW**	36	12	6-Jul-2016
502518	1004244180	**PG256 (F) WW**	36	12	20-Aug-2016
502518	1004420440	**PG256 (F) WW**	36	12	1-Nov-2016
502558	1003036730	**PG256 (F) US**	36	12	24-Mar-2015
502558	1003142000	**PG256 (F) US**	36	12	13-May-2015
502558	1003191650	**PG256 (F) US**	36	12	5-Jun-2015
502558	1003408580	**PG256 (F) US**	36	12	4-Sep-2015
502558	1004047410	**PG256 (F) US**	36	12	31-May-2016
502558	1004139950	**PG256 (F) US**	36	12	6-Jul-2016
502558	1004242300	**PG256 (F) US**	36	12	20-Aug-2016

Table 2: Product with remaining shelf life

REF	Lot#	Product Name	Current Shelf life	Corrected Shelf life	Corrected Expiration Date
502518	1004539950	**PG256 (F) WW**	36	12	20-Dec-2016
502518	1004783760	**PG256 (F) WW**	36	12	7-Apr-2017
502518	1004872350	**PG256 (F) WW**	36	12	16-May-2017
502518	1004896600	**PG256 (F) WW**	36	12	26-May-2017
502558	1004539350	**PG256 (F) US**	36	12	20-Dec-2016
502558	1004783810	**PG256 (F) US**	36	12	7-Apr-2017
502558	1004872380	**PG256 (F) US**	36	12	16-May-2017
502558	1004910650	**PG256 (F) US**	36	12	1-Jun-2017
502558	1004985540	**PG256 (F) US**	36	12	30-Jun-2017

Attachment A: Acknowledgement Form.

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® Benzyl Penicillin PG256 (Ref. 502558, 502518) 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

Attachment 8

URGENT FIELD SAFETY NOTICE
FSCA3193

DECEMBER 15, 2016

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

Dear Laboratory Manager or Laboratory Director,

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 to Patient/User:

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.

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100 Rodolphe Street, Durham, NC 27712
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- When 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.
- 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 Clinical Customer Service representative

Sincerely,

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.

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® Fosfomycin 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

Attachment 9

URGENT FIELD SAFETY NOTICE
FSCA3193

DECEMBER 15, 2016

ETEST® Imipenem IP32 (Ref. 513610, 513618, 513658, 513650) Foam packaging

Dear Laboratory Manager or Laboratory Director,

Our records indicate that your laboratory received the referenced products. This letter is intended for all ETEST® Imipenem IP32 (Ref. 513610, 513618, 513658, 513650) Foam 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® Imipenem IP32 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 thirty-six (36) 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® IP32 (Ref. 513610, 513618, 513658, 513650) Foam packaging after T36 months of shelf-life.

Impact to Patient/User:
As a result of the observed performance issue, there is a potential to obtain a MIC result that is higher than expected after 36 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® IP32 (Ref. 513610, 513618, 513658, 513650) FOAM** packaging (lots listed in 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® IP32 (Ref. 513610, 513618, 513658, 513650)** 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® IP32 (Ref. 513610, 513618, 513658, 513650) that are the following strains:
  - *E coli* ATCC 25922 (Expected range-MIC: 0.064-0.25 µg/mL)
  - *P. aeruginosa* ATCC 27853 (Expected range-MIC: 1-4 µg/mL)
  - *S.pneumoniae* ATCC 49619 (Expected range-MIC: 0.032-0.125 µg/mL)

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- *B tethaiotaomicron* ATCC 29741 (Expected range-MIC: 0.064-0.25 µg/mL)

- The MIC results for those specific strains must fall in the acceptable range to confirm the validity of the QC test and performance of the ETEST strip.

- When replacement product is received, discontinue using and discard impacted **ETEST® IP32 (Ref. 513610, 513618, 513658, 513650)** lots listed in Table 1.

Product with remaining shelf life:

- Identify products listed in Table 2. These products may be used within the revised shelf life requirements as defined in Table 2.
- Correct 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.

- Contact your local bioMérieux representative for product compensation.

    - Please note that **ETEST® IP32 Imipenem (Ref. 412373, 412374) SPB** packaging performs within the specifications until expiration date.

- 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 Clinical Customer Service representative.

Sincerely,

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
513610	1001125240	IP 32 (F) WW	60	36	22-Feb-2015
513610	1001610770	IP 32 (F) WW	60	36	26-Aug-2015
513618	1001193130	IP 32 (F) WW	60	36	22-Feb-2015
513618	1001223300	IP 32 (F) WW	60	36	22-Feb-2015
513618	1001316710	IP 32 (F) WW	60	36	22-Feb-2015
513618	1001377740	IP 32 (F) WW	60	36	22-Feb-2015
513618	1001454060	IP 32 (F) WW	60	36	19-Apr-2015
513618	1001454090	IP 32 (F) WW	60	36	10-Jun-2015
513618	1001527340	IP 32 (F) WW	60	36	10-Jun-2015
513618	1001633670	IP 32 (F) WW	60	36	10-Jun-2015
513618	1001721100	IP 32 (F) WW	60	36	10-Jun-2015
513618	1001801280	IP 32 (F) WW	60	36	10-Jun-2015
513618	1001804930	IP 32 (F) WW	60	36	30-Sep-2015
513618	1002029820	IP 32 (F) WW	60	36	13-Jan-2016
513618	1002234950	IP 32 (F) WW	60	36	11-Apr-2016
513618	1002238110	IP 32 (F) WW	60	36	14-Apr-2016
513618	1002269280	IP 32 (F) WW	60	36	22-Apr-2016
513618	1002476170	IP 32 (F) WW	60	36	14-Jul-2016
513618	1002593870	IP 32 (F) WW	60	36	8-Sep-2016
513618	1002699130	IP 32 (F) WW	60	36	21-Oct-2016
513618	1002702380	IP 32 (F) WW	60	36	22-Oct-2016
513650	1001135740	IP 32 (F) US	60	36	22-Feb-2015
513650	1001154700	IP 32 (F) US	60	36	22-Feb-2015
513650	1001251110	IP 32 (F) US	60	36	22-Feb-2015
513650	1001319240	IP 32 (F) US	60	36	22-Feb-2015
513650	1001333960	IP 32 (F) US	60	36	22-Feb-2015
513650	1001409550	IP 32 (F) US	60	36	10-Jun-2015
513650	1001557360	IP 32 (F) US	60	36	10-Jun-2015
513650	1001574370	IP 32 (F) US	60	36	26-Aug-2015
513658	1001154880	IP 32 (F) US	60	36	22-Feb-2015
513658	1001265150	IP 32 (F) US	60	36	22-Feb-2015
513658	1001368000	IP 32 (F) US	60	36	19-Apr-2015
513658	1001390590	IP 32 (F) US	60	36	19-Apr-2015
513658	1001487630	IP 32 (F) US	60	36	10-Jun-2015
513658	1001609830	IP 32 (F) US	60	36	10-Jun-2015
513658	1001676400	IP 32 (F) US	60	36	10-Jun-2015
513658	1001735190	IP 32 (F) US	60	36	10-Jun-2015
513658	1001811380	IP 32 (F) US	60	36	30-Sep-2015
513658	1002056670	IP 32 (F) US	60	36	13-Jan-2016
513658	1002230910	IP 32 (F) US	60	36	11-Apr-2016
513658	1002478800	IP 32 (F) US	60	36	14-Jul-2016

513658	1002596830	IP 32 (F) US	60	36	8-Sep-2016

Table 2: Product with remaining shelf life.

REF	Lot #	Product Name	Current Shelf Life	Corrected Shelf Life	Corrected Expiration Date
513618	1003066070	IP 32 (F) WW	60	36	6-Apr-2017
513658	1003066090	IP 32 (F) US	60	36	6-Apr-2017

Attachment A: Acknowledgement Form.

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® IP32 (Ref. 513610, 513618, 513658, 513650) 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

Attachment 10

URGENT FIELD SAFETY NOTICE
FSCA3193

DECEMBER 15, 2016

ETEST® Gentamicin GM256 (Ref. 512550, 512510, 512558, 512518) FOAM packaging

Dear Laboratory Manager or Laboratory Director,

Our records indicate that your laboratory received the referenced products. This letter is intended for all ETEST® Gentamicin GM256 (Ref. 512550, 512510, 512558, 512518) FOAM 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® Gentamicin GM256 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 forty-eight (48) 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® Gentamicin GM256 (Ref. 512550, 512510, 512558, 512518) FOAM packaging after T48 months of shelf-life.

Impact to Patient/User:

As a result of the observed performance issue, there is a potential to obtain a MIC result that is higher than expected after 48 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® Gentamicin GM256 (Ref. 512550, 512510, 512558, 512518) FOAM** packaging (lots listed in 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® Gentamicin GM256 (Ref. 512550, 512510, 512558, 512518)** lots listed 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® Gentamicin GM256 (Ref. 512550, 512510, 512558, 512518) that are *E.coli ATCC25922* (Expected range-MIC: 0,25-1 µg/mL) and *P. aeruginosa ATCC27853* (Expected range-MIC:

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0,5-2 µg/mL) strains. The MIC results for those specific strains must fall in the acceptable range to confirm the validity of the QC test and performance of the ETEST strip.

- When replacement product is received, discontinue using and discard impacted **ETEST® Gentamicin GM256 (Ref. 512550, 512510, 512558, 512518)** lots listed Table 1.

Product with remaining shelf life:

- Identify products in Table 2. These products may be used within the revised shelf life requirements as defined in Table 2.
- Correct 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.

- Contact your local bioMérieux representative for product compensation.

    - Please note that **ETEST® GM256 Gentamycin (Ref. 412367, 412368) SPB** packaging performs within the specifications until expiration date.

- 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 Clinical Customer Service representative.

Sincerely,

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
512510	1001970170	GM256 (F) WW	60	48	2-Dec-2016
512510	1002154750	GM256 (F) WW	60	48	2-Dec-2016
512518	1001595660	GM256 (F) WW	60	48	3-Jul-2016
512518	1001707960	GM256 (F) WW	60	48	3-Jul-2016
512518	1001803880	GM256 (F) WW	60	48	25-Oct-2016
512550	1002001100	GM256 (F) US	60	48	2-Dec-2016
512550	1002048740	GM256 (F) US	60	48	2-Dec-2016
512558	1001564260	GM256 (F) US	60	48	3-Jul-2016
512558	1001676270	GM256 (F) US	60	48	3-Jul-2016
512558	1001733240	GM256 (F) US	60	48	3-Jul-2016
512558	1001793760	GM256 (F) US	60	48	3-Jul-2016
512558	1001873760	GM256 (F) US	60	48	25-Oct-2016

TABLE 2: Product with remaining shelf life.

REF	Lot #	Product Name	Current Shelf Life	Corrected Shelf Life	Corrected Expiration Date
512518	1002094250	GM256 (F) WW	60	48	10-Feb-2017
512518	1002229210	GM256 (F) WW	60	48	10-Apr-2017
512518	1002233690	GM256 (F) WW	60	48	11-Apr-2017
512518	1002559790	GM256 (F) WW	60	48	22-Aug-2017
512518	1002684500	GM256 (F) WW	60	48	14-Oct-2017
512518	1002823910	GM256 (F) WW	60	48	15-Dec-2017
512518	1003164040	GM256 (F) WW	60	48	22-May-2018
512518	1003191670	GM256 (F) WW	60	48	5-Jun-2018
512518	1003279330	GM256 (F) WW	60	48	10-Jul-2018
512518	1003604650	GM256 (F) WW	60	48	26-Nov-2018
512518	1004047450	GM256 (F) WW	60	48	30-May-2019
512518	1004157400	GM256 (F) WW	60	48	13-Jul-2019
512518	1004247950	GM256 (F) WW	60	48	22-Aug-2019
512518	1004252220	GM256 (F) WW	60	48	24-Aug-2019
512518	1004528390	GM256 (F) WW	60	48	14-Dec-2019
512518	1004567000	GM256 (F) WW	60	48	5-Jan-2020
512558	1002113320	GM256 (F) US	60	48	10-Feb-2017
512558	1002230930	GM256 (F) US	60	48	11-Apr-2017
512558	1002559800	GM256 (F) US	60	48	22-Aug-2017
512558	1002823250	GM256 (F) US	60	48	15-Dec-2017
512558	1003495040	GM256 (F) US	60	48	9-Oct-2018
512558	1003883840	GM256 (F) US	60	48	22-Mar-2019

512558	1004248160	GM256 (F) US	60	48	22-Aug-2019
512558	1004252230	GM256 (F) US	60	48	24-Aug-2019
512558	1004277880	GM256 (F) US	60	48	5-Sep-2019
512558	1004567040	GM256 (F) US	60	48	5-Jan-2020
512558	1004946070	GM256 (F) US	60	48	12-Jun-2020
512558	1004980260	GM256 (F) US	60	48	23-Jun-2020
512558	1005146190	GM256 (F) US	60	48	8-Sep-2020

Attachment A: Acknowledgement Form.

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® Gentamicin GM256 (Ref. 512550, 512510, 512558, 512518) 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 : .....**

Attachment 11

URGENT FIELD SAFETY NOTICE
FSCA3193

DECEMBER 15, 2016

ETEST® Tobramycin TM256 (Ref. 522718, 522758) FOAM

Dear Laboratory Manager or Laboratory Director,

Our records indicate that your laboratory received the referenced products. This letter is intended for all ETEST® Tobramycin TM256 (Ref. 522718, 522758) FOAM 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® Tobramycin TM256 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 forty-eight (48) 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® Tobramycin TM256 (Ref. 522718, 522758) FOAM packaging after T48 months of shelf-life.

Impact to Patient/User:

As a result of the observed performance issue, there is a potential to obtain a MIC result that is higher than expected after 48 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® Tobramycin TM256 (Ref. 522718, 522758) FOAM** packaging (lots listed in 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® Tobramycin TM256 (Ref. 522718, 522758)** lots listed and 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 organism defined as the stability indicator for ETEST® Tobramycin TM256 (Ref. 522718, 522758) that is *E.coli ATCC25922* strain (Expected range-MIC: 0.25-1 µg/mL). The MIC result for this specific strain must fall in the acceptable range to confirm the validity of the QC test and performance of the ETEST strip.

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- When replacement product is received, discontinue using and discard impacted **ETEST® Tobramycin TM256 (Ref. 522718, 522758)** lots listed and in Table 1.

Product with remaining shelf life:

- Identify products listed in Table 2. These products may be used within the revised shelf life requirements as defined in Table 2.
- Correct 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..
- Contact your local bioMérieux representative for product compensation.
    - Please note that **ETEST® TM256 Tobramycin (Ref. 412478, 412479) SPB** packaging performs within the specifications until its labeled expiration date.
- 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 Clinical Customer Service representative.

Sincerely,

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
522718	1001761650	TM256 (F) WW	60	48	8-Nov-2016
522718	1002112440	TM256 (F) WW	60	48	8-Nov-2016
522758	1001888970	TM256 (F) US	60	48	8-Nov-2016

TABLE 2: Product with remaining shelf life.

REF	Lot #	Product Name	Current Shelf Life	Corrected Shelf Life	Corrected Expiration Date
522718	1002860460	TM256 (F) WW	60	48	7-Jan-2018
522718	1005166530	TM256 (F) WW	60	48	14-Sep-2020
522758	1002281590	TM256 (F) US	60	48	25-Apr-2017
522758	1003590490	TM256 (F) US	60	48	19-Nov-2018

Attachment A: Acknowledgement Form.

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® Tobramycin TM256 (Ref. 522718, 522758) 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 : .....**

Attachment 12

URGENT FIELD SAFETY REMOVAL
FSCA3193

DECEMBER 15, 2016

ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018) FOAM packaging

Dear Laboratory Manager or Laboratory Director,

This letter is intended for all **ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018) FOAM** packaging US & World Wide users. Our records indicate that your laboratory received the following products (reference and lot numbers are included in Table 1 and Table 2).

As a part of our ongoing thorough analysis of the ETEST® product range, we have observed internally two issues with ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018) FOAM that may affect the test performance.

Issue 1: Description: shelf life claims
We have observed internally that the current shelf-life claims of the ETEST® Ceftriaxone TXL32 products listed in Table 2 are not supported by internal testing. As a result there is a potential for an overestimation of the MIC values for specifically *Neisseria gonorrhoeae*. No increase of the complaint trend was observed for these products, but we are taking the precaution of revising the shelf-life claims.

The following has been identified

- ⇨ QC failure (MICs above the upper QC limit) for some Quality Control strains listed in the Instructions For Use on ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018) FOAM packaging.

Impact to Patient/User:
As a result of the observed performance issue, there is a potential to obtain a MIC result that is higher than expected. 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 Non-Susceptible or a false Resistant result.

Required actions:
The following recommendations require your immediate attention to ensure the product will continue to perform per its labeled performance specifications, within its revised shelf-life of twelve (12) months.

- Identify impacted lots of **ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018) FOAM** packaging (lots listed in Table 1 below) which are now expired after shelf-life reduction.
- Immediately order the replacement products appropriate for your institution.
- Until replacement product is available Laboratories may continue to use their now expired strips with the following recommendations:
  - o Laboratories should continue to follow their current QC procedures for **ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018)** for the lots listed in Table 1 in accordance with CLIA and local regulatory requirements, with a modification to increase the

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frequency of QC testing to weekly or every day of use if previous QC testing exceeds one week.

- Laboratories should include in the QC testing the strain (*N. gonorrhoeae* ATCC 49226) defined as the stability indicator for ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018). The MIC result for this specific strain must fall in the acceptable range to confirm the validity of the QC test and performance of the ETEST with the clinical isolate.
- Only report results if all QC is in the acceptable ranges.

- When replacement product is received, discontinue using and discard impacted **ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018)** (listed in Table 1) whatever the product shelf-life.

- Please note that the **FOAM** packaging manufacturing has been already discontinued and all customers will be transitioned to **Single Pack Blister (SPB) packaging.**

Issue 2: Description: A potential performance issue on strain categorization

The following was identified:

- For *Streptococcus pneumoniae* meningitis strains: based on 2016 **CLSI** guidelines a reduced MIC value might be obtained with ETEST® TXL32 (SPB and FOAM packaging) that could lead to a susceptible categorization instead of intermediate categorization (Minor Error) or resistant categorization (Very Major Error) for clinical strains as compared to broth microdulution (BMD) reference method.

- For *Streptococcus pneumoniae* strains (meningitis and non-meningitis): based on 2016 **EUCAST** guidelines a reduced MIC value could be obtained with ETEST® TXL32 SBP and FOAM packaging) leading to a susceptible categorization instead of intermediate categorization for clinical strains as compared to BMD reference method: Minor error.

Impact to Patient/User:

There is a potential to obtain:

- A susceptible result instead of an intermediate result (Minor Error) or resistant result (Very Major Error) for *Streptococcus pneumoniae* meningitis strains with ETEST® TXL32 SPB and FOAM packaging compared to the BMD reference method using 2016 **CLSI** guidelines.
- A susceptible result instead of an intermediate result (Minor Error) for *Streptococcus pneumoniae* strains with ETEST® TXL32 SPB and FOAM packaging compared to the BMD reference method and based on 2016 **EUCAST** guidelines.

Recommendations for users under CLSI guidelines: To inform customer that there is a potential to obtain a false susceptible result instead of intermediate or resistant result compared to the BMD reference method for *Streptococcus pneumoniae* meningitis based on 2016 CLSI breakpoints with ETEST® TXL32 (FOAM and SPB packaging). Laboratories can continue to use ETEST® TXL32 for *Streptococcus pneumoniae* meningitis when applying the following recommendations:

- **Under the following conditions ETEST® TXL32 results can be directly reported for *Streptococcus pneumoniae* (CLSI meningitis):**
  - Isolate tests penicillin susceptible (MIC ≤0.06 μg/ml) and ceftriaxone susceptible (**ETEST® TXL32** MIC ≤0.5 μg/ml)
  - Isolate tests penicillin resistant (MIC ≥0.12 μg/ml) and ceftriaxone resistant (**ETEST® TXL32** ≥ 2 μg/ml)

- **For isolates testing penicillin resistant (MIC ≥0.12 μg/ml) and ceftriaxone susceptible (ETEST® TXL32 MIC ≤0.5 μg/ml) or intermediate (ETEST® TXL32 MIC=1 μg/ml), the ceftriaxone MIC should be confirmed using an alternative MIC test method.**

Recommendations for users under EUCAST guidelines: to inform the customer that there is a potential to obtain a false susceptible result instead of intermediate result for *Streptococcus*

pneumoniae strains compared to the BMD reference method based on 2016 **EUCAST** guidelines for ETEST® TXL32 (FOAM and SPB packaging). Laboratories can continue to use ETEST® TXL32 for *Streptococcus pneumoniae* when applying the following the recommendations:

- Laboratories should verify the result by an alternative method for each *Streptococcus pneumoniae* isolate (meningitis and non-meningitis) with an **ETEST® TXL32** MIC ≥0.5 μg/ml). This verification **is not needed** for isolates that are known to be fully susceptible to benzylpenicillin (MIC ≤0.06 μg/ml) or that have an oxacillin zone diameter >8 mm.

- 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.
- Alternative methods of testing for Ceftriaxone and Streptococcus pneumonia are available, please contact bioMérieux for automated alternate methods.
- 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 Clinical Customer Service representative.

Sincerely,

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

REF	Product Name	Lot#
507018	TXL 32 (F) WW	1002940880
507018	TXL 32 (F) WW	1003182290
507018	TXL 32 (F) WW	1003813700
507018	TXL 32 (F) WW	1003851130
507018	TXL 32 (F) WW	1003953490
507018	TXL 32 (F) WW	1004239880
507018	TXL 32 (F) WW	1004316460
507018	TXL 32 (F) WW	1004527210
507018	TXL 32 (F) WW	1004755930
507018	TXL 32 (F) WW	1004828450
507018	TXL 32 (F) WW	1004876850
507018	TXL 32 (F) WW	1004919010
507058	TXL 32 (F) US	1002940890
507058	TXL 32 (F) US	1003128150
507058	TXL 32 (F) US	1003361950
507058	TXL 32 (F) US	1003849820
507058	TXL 32 (F) US	1004041790
507058	TXL 32 (F) US	1004239890
507058	TXL 32 (F) US	1004395510
507058	TXL 32 (F) US	1004525370
507058	TXL 32 (F) US	1004756050
507058	TXL 32 (F) US	1004828430
507058	TXL 32 (F) US	1004876860
507058	TXL 32 (F) US	1004919030

Attachment A: Acknowledgement Form.

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® Ceftriaxone TXL32 (Ref. 507058, 507018) 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 : .....**