



Customer letter for all customer except USA

Our references:
Etest Ertapenem – References:
531610, 531618, 412332
- Lots: See Annex 1
IMPORTANT: Product Removal Notice

Address City,
Date:

Dear Valued bioMérieux Customer,

You are an user of Etest Ertapenem Products, thank you for choosing bioMérieux solutions.
Our records indicate that you have received at least one of following Reference products: (Lots: see Annex 1)

Reference	Product name
531610	Etest ERTAPENEM - Foam ETP 32 – 30 tests
531618	Etest ERTAPENEM- Foam ETP 32 – 100 tests
412332	Etest ERTAPENEM ETP 32 – Single pack of 30 tests

Description of Issue:

bioMérieux identified a performance issue on the Etest Foam Ertapenem (Reference 531610 and 531618) and Etest Single pack Ertapenem (Ref 412332). These strips didn't give the correct MIC (Minimum Inhibitory Concentration) for some of Quality Control strains.

Indeed, the MIC results were out of range high according to the MIC specification described in the Quality Control procedure. The investigation confirms that this issue appears over the time while the MIC results were conform at the time of the batch release and to lead to a performance issue by overestimating the MICs
Investigations are still ongoing in order to identify the root cause.

Impact to customer:

The potential risk associated with the reported issue is an over-estimation of MIC for *Enterobacteriaceae* and *non-Enterobacteriaceae*.

- **For non-Enterobacteriaceae** (Quality Control purpose), the MIC shift over the time can be greater than +1 dilution when compared to the MICs initially obtained at the time of the release.
- **For Enterobacteriaceae:** the over-estimation of MIC can change the category result of isolates having MIC equal or close to the breakpoint. As such, isolates with **MIC at 0.5 µg/ml** (current Susceptible CLSI and EUCAST breakpoint) can be interpreted **Intermediate instead of Susceptible**, while those having a **MIC at 1 µg/ml** can be interpreted **Resistant instead of Intermediate** (with both CLSI and EUCAST breakpoints).

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This performance issue leading to this over-estimation of MIC can be detected using the Quality control as recommended in the Etest package insert.

Required actions:

As conclusion, we request you to take the following action at this time:

1. Ensure this letter and guidance has been distributed and reviewed by all appropriate personnel within your organization.
2. If you are still in possession of kits of Etest Foam Ertapenem and Etest Single Pack Ertapenem (References– Lots: see annex 1) discontinue to use them and destroy the kits
3. Fill out and return the Acknowledgement Form by fax for product replacement. bioMérieux will provide replacement kits as soon as a new batch of Etest Ertapenem is available.

Enter Local Contact: XXXXX

bioMérieux is committed to provide our customers with the highest quality product possible. We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Thank you for your continued use of bioMérieux products,



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ACKNOWLEDGEMENT FORM - DESTRUCTION CERTIFICATE

TO BE RETURNED TO YOUR CUSTOMER SERVICE

fax :

Name of the laboratory:

City:

Customer number:

I acknowledge the receipt of bioMérieux letter informing about a performance issue on strips of Etest Foam Ertapenem (Reference 531610 and 531618) and Etest Single Pack Ertapenem (Ref 412332) and that I have to destroy the kits still in my stock.

Product name	Reference	Lot number	Number of kits destroyed
531618 Etest ERTAPENEM Foam ETP 32 – 100 tests	531618	1001510940	
		1001427840	
		1001274050	
		1001223880	
		1001062790	
		1000789490	
		1001762710	
		1001707210	
		1001634370	
		1001596230	
		1002054430	
		1000924550	
		1001223870	

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Product name	Reference	Lot number	Number of kits destroyed
531610 Etest ERTAPENEM Foam ETP 32 – 30 tests	531610	1001157880	
		1001101360	
		1000853690	
		1000754440	
		1000680540	
		1000614830	
		1001295970	
		1001960650	
		1002195290	
		1001804050	
		1001721710	
		1001707200	
		1001634360	
		1001567650	
1001496030			
412332 Etest ERTAPENEM ETP 32 – Single pack of 30 tests	412332	1001417010	
		1001324200	
		1002110560	
		1002389880	

DATE

SIGNATURE :

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Annex 1

Table 1:

Product name	Reference packaging	Lot number packaging	Expiry date	Reference and lot number inside packaging
531618 Etest ERTAPENEM Foam ETP 32 – 100 tests	531618	1001510940	2014-JUN-07	Reference : 51103168 Lot :1000472840
		1001427840	2014-JUN-07	
		1001274050	2014-JUN-07	
		1001223880	2014-JUN-07	
		1001062790	2014-JUN-07	
		1000789490	2014-JUN-07	
		1001762710	2015-MAR-20	Reference : 51103168 Lot :1001173610
		1001707210	2015-MAR-20	
		1001634370	2015-MAR-20	
		1001596230	2015-MAR-20	
		1002054430	2015-DEC-06	Reference : 51103168 Lot :1001897090
531610 Etest ERTAPENEM Foam ETP 32 – 30 tests	531610	1000924550	2014-JUN-07	Reference : 51103160 Lot :1000472830
		1001223870	2014-JUN-07	
		1001157880	2014-JUN-07	
		1001101360	2014-JUN-07	
		1000853690	2014-JUN-07	
		1000754440	2014-JUN-07	
		1000680540	2014-JUN-07	
		1000614830	2014-JUN-07	
		1001295970	2014-JUN-07	Reference : 51103160 Lot :1001895910
		1001960650	2015-DEC-06	
		1002195290	2015-DEC-06	
		1001804050	2015-MAR-20	
		1001721710	2015-MAR-20	
		1001707200	2015-MAR-20	
		1001634360	2015-MAR-20	
1001567650	2015-MAR-20	Reference : 51103160 Lot :1001173600		
1001496030	2015-MAR-20			
1001417010	2015-MAR-20			
1001324200	2015-MAR-20			
412332 Etest ERTAPENEM ETP 32 – SPB pack of 30 tests	412332	1002110560	2016-FEB-27	N/A
		1002389880	2016-JUN-11	