Report Form
Manufacturer's Field Safety Corrective Action Report

Medical Devices Vigilance System

(MEDDEV 2.12/1 rev 8)

v.01.13

1. Administrative information	
To which NCA(s) is this report being sent? Agence Nationale du Médicament et des produits de Santé (ANSM) 143/147 boulevard Anatole France 93285 SAINT-DENIS CEDEX	
Type of report ☒ Initial report ☐ Follow up report ☐ Final report	
Date of this report 09-NOV-2016	
Reference number assigned by the manufacturer FCA 3204	
FCA reference number assigned by NCA Not yet known	
Incidence reference number assigned by NCA N/A	
Name of the co-ordinating national competent authority (if applicable) N/A	
2. Information on submitter of the report	
Status of submitter ☒ Manufacturer ☐ Authorised representative within EEA, Switzerland and Turkey ☐ Others (identify the role):	
3. Manufacturer information	
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E-mail anne-sophie.auberty@biomerieux.com	Country France
4. Authorised representative information	
Name N/A	
Contact name N/A	
Address N/A	

Postcode N/A	City N/A
Phone N/A	Fax N/A
E-mail N/A	Country N/A

5. National contact point information

National contact point name QMR Benelux	
Name of the contact person Nancy Peeters	
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6. Medical device information

Class

☐	AIMD Active implants	☐	IVD Annex II List A
☐	MDD Class III	☐	IVD Annex II List B
☐	MDD Class IIb	☐	IVD Devices for self-testing
☐	MDD Class IIa	☒	IVD General
☐	MDD Class I		

Nomenclature system (preferable GMDN) GMDN	Nomenclature code 44448
Nomenclature text Antibiotic susceptibilitytesting kit, bacterial	
Commercial name/brand name/make Etest® MBL MP/MPI 8/2 B30	
Model number N/A	Catalogue number: 411361
Serial number(s) N/A	lot/batch number(s) 1004504020 1004724840
Device Manufacturing date 1004504020; 04-DEC-2015 1004724840; 11-MAR-2016	Expiry date 1004504020; 16-NOV-2016 1004724840; 23-FEB-2017
Software version number (if applicable) N/A	
Accessories/associated device (if applicable) N/A	
Notified body (NB) ID- number N/A	

7. Description of FCA

Background information and reason for the FCA:

Product description:

Etest® is a quantitative technique for determining the Minimum Inhibitory Concentration (MI C) of antimicrobial agents against microorganisms and for detection of resistance mechanisms.

The Etest MBL MP/MPI strip consisting of Meropenem (MP) / Meropenem + EDTA (MPI) is designed to detect Metallo ß-Lactamases (MBL) in Enterobacteriaceae. Positive phenotypes should be sent to a reference laboratory for confirmation with genotypic methods.

The Etest MBL MP/MPI strip consists of a thin, plastic carrier calibrated with reading scales in µg/mL on one side (a) while the opposite surface carries two predefined gradients (b). MP stands for meropenem (0.125-8 µg/mL) and MPI meropenem (0.032-2 µg/mL) plus a constant level of EDTA.

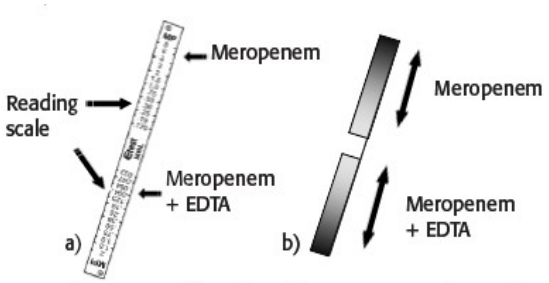

Figure 1. Configuration of Etest MBL MP/MPI strip

Description of the issue:

The bioMérieux UK subsidiaryreported to the International Distribution Centre (IDC) that they had observed a non-conformity on Etest MBL MEROPENEME + EDTA 8/2 (Ref. 411361) and on Etest MBL MP/MPI 8/2 WW B100 (Ref. 411362) packaging:

- These products should be shipped on dry ice (solid carbon dioxide), according to procedure 000022 - *Thermo sensitive products – List of products requiring additional shipping rules*
- The products were received by the subsidiary without this special packaging.

Following this report, **investigation CAPA PR# 1045072** was opened to identify the root cause of the anomaly and to prevent the issue reoccurring.

The investigation identified that 3 shipments containing the impacted products were actually in the field. The investigation states that the list of affected products is described above (Section 6 Medical Device Information).

This anomaly is not linked to a manufacturing issue. It occurred at the point of prepa ration of orders and led to a storage issue. The anomalycould not occur with other references in the Etest Product range as no other references from this range require to be transported on dry ice.

The investigation described the Time Out of Range (TOR) as the following:

The packages containing frozen products are packed at the IDC. The products are labeled with a sticker indicating "freeze immediately upon arrival". They are stocked in the IDC freezer at -19/-31°C and are transferred to XPO (freight forwarding subcontractor) in the morning for departure that day. The packages can potentially experience a maximum TOR of 15 hours at 15-25°C what represents 3 hours at the IDC and 12 hours at the XPO (road shipment). Products are then transported to the recipient subsidiary in trucks monitored at 2-8°C. The time of this part of the shipment is not precisely known.

Based on the stability study, investigators showed that the defined TOR experienced by the products have the following impact:

- The deterioration of Meropenem (MP) is proportionallythe same as Meropenem + EDTA (MPI), according to Quality Control strains tested for this stabilitystudy.
- The impact of this deterioration is an increasein **Non-Determinable (ND) results**.
- There is no risk of a false negative or false positive results as the deterioration of the test will provide a Non Determinable result.

According to the Package Insert:
No ellipse/zone indicates a Non determinable result as the Inhibitory Concentrations (IC) is >8/>2.

Strains with non-determinable (ND) results should be further investigated with genotypic methods.

Two root causes have been identified for this issue:

- Insufficient operator training,
- Insufficient communication when the packaging instructions are modified,

Incomplete procedure has been assessed as an aggravating factor.

Corrective and Preventive actions have been defined to prevent the issue reoccurring. CAPA PR 1045072
All the other shipments, except those identified in the CAPA, were transported on dry ice.

Impact to customer:

The referenced products are IVD products. Incorrect storage conditions result in an increase in Non -Determinable results and does not lead to false results. However, Non Determinable results could lead to a delay in obtaining a result.
According to the Health Hazard Assessment the following has been determined :

- The severity of the risk of no results that could lead to a delay in results is considered **INSIGNIFICANT;** temporaryor reversible (without medical intervention) for both the population at risk and the normal population. There is no risk of false results.

- The probabilityof occurrence is **OCCASIONAL;** relative few occurrences for the population at risk and **REMOTE;** unlikelyto occur but is possible for the normal population.

Based on the severity and probability, the overall risk of the identified hazard is **MINOR.**

Description and justification of the action (corrective/preventive):

Considering the increase in Non-Determinable results (no results), the Field Action Board determined taking action in the field is appropriate in the form of removing non-conforming products from the field to resolve the identified issue.
Affected subsidiaries (PT, CZ, NL) will be instructed to discard all the products remaining in their inventory.
The customer letter will inform customers about the issue and instruct them to discard the impacted products remaining in their inventory.
FCA 3204 has been implemented in the field on 09NOV2016.

A CAPA 1045072 was opened.

Advice on actions to be taken by the distributor and the user

The Field Corrective Action (FCA) 3204 was issued on 09-NOV-2016.

Progress of FCA, together with reconciliation data (Mandatory for a Final FCA)

Attached please find	FSN Status
☒ Field Safety Notice (FSN) in English ☐ FSN in national language ☐ Others (please specify):	☐ Draft ☒ Final

Time schedule for the implementation of the different actions

Next report : end of DEC 2016

These countries within the EEA and Switzerland and Turkey are affected by this FSCA

Within EEA, Switzerland and Turkey:

☐ AT	☐ BE	☐ BG	☐ CH	☐ CY	☒ CZ	☐ DE	☐ DK	☐ EE	☐ ES
☐ FI	☐ FR	☐ GB	☐ GR	☐ HU	☐ IE	☐ IS	☐ IT	☐ LI	☐ LT
☐ LU	☐ LV	☐ MT	☒ NL	☐ NO	☐ PL	☒ PT	☐ RO	☐ SE	☐ SI
☐ SK	☐ TR								

Candidate Countries:
☐ HR

☐ All EEA, Candidate Countries, Switzerland and Turkey

Others:

8. Comments

N/A

I affirm that the information given above is correct to the best of my knowledge.

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Signature		
Nancy Peeters	Brussels	10-NOV-2016
Name	City	Date

Submission of this reportdoes not, in itself, representa conclusion by the manufacturer and/or authorized representative or the national competentauthority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.