

21st December 2018

URGENT FIELD SAFETY NOTICE

ThermoScientific™ Oxoid™ Meropenem 32 M.I.C.E. strip, MA0121D&F

<u>Lot</u>	<u>Exp date</u>
2356765	31/07/2019
2341306	30/06/2019

Customers are to be advised of the following:

DESCRIPTION

An internal technical investigation has confirmed that ThermoScientific™ Oxoid™ Meropenem M.I.C.E. Strips MA0121 lot 2356765 are producing high, out of specification MIC results when tested with *Staphylococcus aureus* ATCC®29213™, *Staphylococcus aureus* ATCC®25923™, *Pseudomonas aeruginosa* ATCC®27853™ and *Enterococcus faecalis* ATCC®29212™.

Lot 2341306 is producing high, out of specification results with *Staphylococcus aureus* ATCC 25923. Other quality control organisms are satisfactory.

Continued use of this lot could result in minor delays in overall effective therapy.

RISK TO HEALTH

We believe the clinical risk is expected to be low to moderate for patients infected with *P. aeruginosa* and very low for patients infected with *S. aureus*.

For patients infected with *P. aeruginosa* the immediate health consequences are expected to be low to moderate. The immediate clinical consequences may be a delay in appropriate change to alternative agents if the patient is failing clinically. Infections caused by *P. aeruginosa* are commonly treated with combination therapy which should mitigate the risk.

The clinical risk is expected to be very low for patients infected with *S. aureus*. Infections caused by *S. aureus* are commonly treated with either a combination therapy or with other beta-lactam agents which should mitigate the risk.

ACTIONS TO BE TAKEN

Our records indicate that you have received the above product.

Accordingly, in keeping with our Quality Policy, we request that you destroy any remaining inventory of the lot listed above and contact Customer Services or your local distributor regarding any necessary replacements.. Requirement for review of reported test results should be determined by the appropriate technical expert.

The Medicines and Healthcare products Regulatory Agency (MHRA) has been informed of this Field Safety Corrective Action.

This notice needs to be passed on to all who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. If you have any questions, please contact our Technical Support Department on +44 (0)1256 694238, or at microbiology.techsupport.uk@thermofisher.com.

You should complete the accompanying Acknowledgement Form in regard to inventory you have received and/or which is still in stock.

We appreciate your immediate attention to this matter and apologise for any inconvenience this may have caused.

Yours sincerely,



James H Filer
Vice President, Quality and Regulatory, MBD

21st December 2018

ACKNOWLEDGEMENT FORM

**Re. ThermoScientific™ Oxoid™ Meropenem 32 M.I.C.E. strip, MA0121D&F, Lot 2356765
Exp. 31.07.2019 & 2341306 Exp. 30/06/2019**

Dear Customer,

Please find enclosed a copy of the Urgent Field Safety Notice (F.S.N.) regarding ThermoScientific™ Oxoid™ Meropenem 32 M.I.C.E. strip, MA0121D&F, Lot 2356765 Exp. 31.07.2019 & 2341306 Exp. 30/06/2019, manufactured and sold between July 2018.

Accordingly, in keeping with our Quality Policy, we request that you destroy any remaining inventory of the lot listed above and contact Customer Services or your local distributor regarding any necessary replacements. Requirement for review of reported test results should be determined by the appropriate technical expert.

To meet regulatory requirements of the IVD Directive, I would be grateful if you would confirm receipt of this letter and F.S.N by emailing back a completed, signed copy of this Acknowledgement Form to the Customer Services Department on Fax no. +44(0)1256 479525 by 18th January 2019.

If you require any Technical Assistance please contact our Technical Support Team on 01256 694238 or at microbiology.techsupport.uk@thermofisher.com. Any other assistance, please contact your Customer Services Representative on **Contact No.**

Yours sincerely,

Signed :
Title :
Company :

CONFIRMATION OF RECEIPT

I confirm receipt of the F.S.N. for ThermoScientific™ Oxoid™ Meropenem 32 M.I.C.E. strip, MA0121D&F, Lot 2356765 Exp. 31/07/2019 & 2341306 Exp. 30/06/2019, dated 21st December 2018.

I confirm that the product has been destroyed. **Please confirm No. of units destroyed.....**

I require replacement packs/Credit to be issued (Please indicate if none required)

Signed..... Name (please print).....

Position..... Date.....

Email Address/Telephone Number.....