

8th August 2019

URGENT FIELD SAFETY NOTICE

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

<u>Lot</u>	<u>Exp. date</u>
2481054	31/03/2020
2475332	29/02/2020
2457512	31/01/2020
2434303	31/12/2019
2434301	31/12/2019
2431420	30/11/2019
2430549	30/11/2019
2430548	30/11/2019
2430550	30/11/2019
2430546	30/11/2019
2430547	30/11/2019
2430544	30/11/2019
2430545	30/11/2019

Customers are to be advised of the following:

DESCRIPTION

An internal technical investigation has confirmed that ThermoScientific™ Oxoid™ Meropenem 32 M.I.C.Evaluator strips, MA0121D&F, are producing high out of specification MIC results when tested with all quality control organisms as stated in the product specification. This issue affects all lots listed above.

Continued use of these lots could result in minor delays in overall effective therapy.

RISK TO HEALTH

The M.I.C.Evaluator (M.I.C.E.™) strips are a range of devices for the accurate determination of the minimum inhibitory concentration (MIC) of an antimicrobial for a test organism.

We believe the clinical risk is expected to be moderate with no significant long term consequences. An immediate consequence of a high MIC result for meropenem might be the reporting of false resistance. This may cause a delay to treatment while other test methods are used to establish if false resistance has occurred, and the potential requirement for a change of antimicrobial treatment.

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 lots 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
Microbiology Products

8th August 2019

ACKNOWLEDGEMENT FORM

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

Dear Customer,

Thermo Fisher Scientific, Microbiology, has taken the decision to recall ThermoScientific™ Oxoid™ Meropenem 32 M.I.C.E. Strips, manufactured and sold between November 2018 and July 2019.

To meet regulatory requirements of the IVD Directive, I would be grateful if you would confirm receipt of this Field Safety Notice by emailing a completed, signed copy of this Acknowledgement Form to the vigilance email, mbd.vigilance@thermofisher.com, or Customer Services Department at Fax no. +44(0)1256 479525 by **5th September 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, dated 8th August 2019.

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.....