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URGENT FIELD SAFETY NOTICE

ThermoScientific™ Oxoid™ Ceftriaxone 32 M.I.C.E. strip, MA0122D&F,

Lot	Exp. date
2380270	31/08/2019
2341066	30/06/2019

Customers are to be advised of the following:

DESCRIPTION

An internal technical investigation has confirmed that ThermoScientific™ Oxoid™ Ceftriaxone 32 M.I.C.Evaluator strip, MA0122D&F, lot 2380270 is producing high out of specification MIC results when tested with *Staphylococcus aureus* ATCC®29213™ and *Escherichia coli* ATCC®25922™ and lot 2341066 is producing high out of specification MIC results when tested with *Staphylococcus aureus* ATCC®29213™.
Other quality control organisms are satisfactory.

Continued use of this lot 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 low and there are no significant long term consequences. An immediate consequence of a high out of range quality control result for ceftriaxone might be the reporting of false resistance for *S. aureus*. However, breakpoints of cephalosporins, including ceftriaxone, for *S. aureus* have been removed and are now related to results of tests against cefoxitin. All cefoxitin-resistant *S. aureus* are considered resistant to all beta-lactam agents, whereas cefoxitin-susceptible strains are considered likely to be clinically susceptible to these agents. So the clinical effect of this out of range QC result is unlikely to have an effect on the reporting of results for ceftriaxone and S. aureus.

The similar out of range QC result for *E. coli* QC suggest that false resistance is unlikely since the resistant breakpoint is ≥ 4 mg/L, and MICs of clinical strains are rarely greater than 0.5 mg/L therefore the clinical risk is very low.

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 (amend accordingly) 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