Thermo Fisher Scientific
Microbiology
Wade Road
Basingstoke
Hampshire
RG24 8PW
Phone: +44 (0) 1256 841144
Fax: +44 (0) 1256 814626
www.thermofisher.com

17th August 2016

URGENT FIELD SAFETY NOTICE

Thermo Scientific™ Oxoid™ CT1629B CAZ10 CEFTAZIDIME BATCH 1426486

Customers are to be advised of the following:

DESCRIPTION

A technical investigation has confirmed that Thermo Scientific™ Oxoid™ CT1629B CAZ10 ceftazidime Batch 1426486 may contain discs with a reduced concentration of antibiotic that may impact on performance. Testing with *Pseudomonas aeruginosa* ATCC 27853 (EUCAST quality control organism) returned lower than specified zones of inhibition.

Continued use of this lot could result in quality control failures, delayed results or incorrect results reporting (false resistance).

RISK TO HEALTH

This antimicrobial susceptibility disc has been made available to indicate microorganism sensitivity to ceftazidime using the disc diffusion method

A false ceftazidime resistance result with a clinical strain of *P. aeruginosa* may cause a potential delay in effective treatment although in some cases, patients suspected of having a *P. aeruginosa* infection may be treated with ceftazidime empirically. A false resistant result is likely to cause a change to an alternative agent to which the isolate has tested susceptible.

For this type of infection there are other options for therapy i.e. piperacillin-tazobactam, carbapenems and fluoroquinolones. In addition, ceftazidime resistance is an increasing issue and therefore, this antibiotic is less often used for primary therapy.

Not all of the lot is affected by this issue and successful customer quality control may identify a failure before use.

For these reasons we believe the risk is low.

ACTIONS TO BE TAKEN

Our records indicate that you have received the above product lot.

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

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The Medicines and Healthcare products Regulatory Agency (MHRA) have 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 Acknowledgment 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