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3rd November 2015

URGENT FIELD SAFETY NOTICE

OXOID ANTIMICROBIAL SUSCEPTIBILITY TESTING DISC

CEFOXITIN FOX30 CT0119B LOTS 1689092 & 1689093: D.O.M 02.06.2015

Customers are to be advised of the following:

DESCRIPTION

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

An internal technical investigation by Oxoid Limited, part of Thermo Fisher Scientific, has confirmed that Oxoid Antimicrobial Susceptibility Testing Disc Cefoxitin FOX30 CT0119B Lots 1689092 & 1689093 may contain discs that have insufficient concentration of antibiotic. We have identified that the low concentration may impact on the performance of the disc against *Escherichia coli* and *Neisseria gonorrhoeae* quality control organisms resulting in lower than expected zones of inhibition. Performance with the *Staphylococcus aureus* QC organism is currently within specification.

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

RISK TO HEALTH

Cefoxitin 30 AST discs are used almost exclusively as a screen to identify possible extended-spectrum beta-lactamases (ESBL) or AmpC strains of *Enterobacteriaceae*, particularly *E. coli*. Many laboratories now use additional investigations e.g. ESBL/AmpC disc combinations to clarify the initial disc screen, but results may be reported as presumptive before this information is available. Therefore, an incorrect report could result in a delay in the most appropriate treatment being utilised or a failure to implement appropriate infection control practices. For these reasons we believe the clinical risk is moderate.

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 inspect your stocks and destroy any remaining inventory of the lots 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, MBD