

28th October 2015

URGENT FIELD SAFETY NOTICE

OXOID ANTIMICROBIAL SUSCEPTIBILITY TESTING DISC

CT0024B GENTAMICIN (CN10), LOT 1686823: DOM: 01/06/2015

Customers are to be advised of the following:

DESCRIPTION

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

An internal technical investigation by Oxoid Limited, part of Thermo Fisher Scientific, has confirmed that CT0024B Gentamicin (CN10), Lot 1686823, may contain some discs that have insufficient concentration of antibiotic. This could result in an incorrect test reading due to small or absent, zones of inhibition. Continued use of this lot could result in quality control failures, delayed results or false resistance reporting.

We believe a low number of discs within the batch are impacted and therefore the likelihood of encountering an affected disc is low.

RISK TO HEALTH

As clinical isolates are typically simultaneously tested against one or more aminoglycosides, an anomalous result showing a completely resistant gentamicin isolate should prompt further investigation and may result in an alternative suitable antibiotic being selected. If the issue was identified during laboratory quality control procedures then the corresponding clinical test results would be considered invalid and a retest initiated.

The likely outcome associated with a device failure, therefore, would be a delay to test results and we believe the clinical risk is 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 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.

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