

1st December 2015

URGENT FIELD SAFETY NOTICE

OXOID ANTIMICROBIAL SUSCEPTIBILITY TESTING DISC

QD15 QUINUPRISTIN / DALFOPRISTIN, CT1644B LOT 1675622: D.O.M 08.05.2015

Customers are to be advised of the following:

DESCRIPTION

This antimicrobial susceptibility disc has been made available to indicate microorganism sensitivity to Quinupristin / Dalfopristin 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 QD15 Quinupristin / Dalfopristin, CT1644B Lot 1675622 may contain a small number of discs that produce variable results. Not all of the lot is affected however we have identified that some discs may produce larger than expected or unexpected zones of inhibition.

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

RISK TO HEALTH

Quinupristin / Dalfopristin is indicated for use in the treatment of Vancomycin Resistant *Enterococcus Faecium* and less commonly Vancomycin resistant *Staphylococcus aureus*. Although there are breakpoints for Quinupristin / Dalfopristin provided by EUCAST and CLSI, use of this antibiotic to treat patients is not routine as there are other, more suitable therapeutic agents available (e.g. Daptomycin, Linezolid). A false sensitivity result, however may lead to under reporting of resistance.

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.

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