

18th November 2015

URGENT FIELD SAFETY NOTICE

OXOID ANTIMICROBIAL SUSCEPTIBILITY TESTING DISC

PENICILLIN G (P1), CT0152B LOT 1675623: 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 Penicillin G 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 Penicillin G (P1), CT0152B lot 1675623 may contain a small number of discs that produce variable results. Not all of the lot is affected however our investigation identified that the size of the inhibition zone varied significantly with some discs producing larger than expected, unexpected or irregular zones of inhibition.

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

RISK TO HEALTH

In EUCAST methodology, Penicillin G (P1) discs are primarily used to screen organisms for betalactamase production. Results from screening are used to predict susceptibility/resistance of organisms to a number of important betalactam antibiotics (e.g. Ampicillin, Amoxicillin, Amoxicillin-clavulanic) and to detect betalactamase and PBP-mediated resistance. A false sensitivity result may lead to under reporting of resistance and inappropriate patient treatment.

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