

24th March 2016

Thermo
S C I E N T I F I C

URGENT FIELD SAFETY NOTICE

ThermoScientific™ Oxoid™ Antimicrobial Susceptibility Test Disc Ticarcillin/Clavulanic Acid (TIM85) CT0449B – All Lots

Customers are to be advised of the following:

DESCRIPTION

Internal investigations have identified variability in concentration of lots of Thermo Scientific™ Oxoid™ Antimicrobial Susceptibility Test disc Ticarcillin/Clavulanic Acid (TIM85) CT0449, currently in the market place. Active compound degradation over shelf life may result in lower than specified concentration leading to 'out of specification' performance results (small zone size).

Continued use of this product could result in delayed or false resistance, reporting.

RISK TO HEALTH

This antimicrobial susceptibility disc has been made available to indicate sensitivity to Ticarcillin/Clavulanic Acid by the disc diffusion method.

From a clinical perspective, Ticarcillin–Clavulanic acid has been largely supplanted by Piperacillin–Tazobactam. It is still used for the treatment of some *Stenotrophomonas* infections but is rarely used for *Pseudomonas* infections because of superior activity of other agents, including Piperacillin–Tazobactam.

Quality control testing using an indicator strain sensitive to both the ticarcillin and clavulanic acid concentration combined e.g. *Escherichia coli* ATCC 35218, should readily identify deterioration in concentration. Refer to CLSI or EUCAST standards for interpretation of this QC strain. The result of testing clinical isolates would be potential false resistance; however there are alternative effective agents available for therapy. Delays in treatment are likely to be short since laboratories can report other effective agents until the problem is resolved.

For these reasons we believe the clinical risk is low.

The Medicines and Healthcare products Regulatory Agency (MHRA) have been informed of this Field Safety Corrective Action.

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 destroy any remaining lots of the product code mentioned above and contact Customer Services or your local distributor regarding alternative products. Requirement for review of reported test results should be determined by the appropriate technical expert.

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