

19 April 2018

URGENT FIELD SAFETY NOTICE

ThermoScientific™ Oxoid™ OX1 Oxacillin, CT0159B, Lot 2248254 D.O.M. 22.11.2017

Customers are to be advised of the following:

DESCRIPTION

A technical investigation has confirmed that some packs of Thermo Scientific™ Oxoid™ OX1 Oxacillin, CT0159B, lot 2248254 may contain individual cartridges of a different product, i.e. CT0417B, CRO30 CEFTRIAZONE.

Each individual cartridge is correctly labelled.

If the incorrect disc was used then it could cause delay in reporting the correct antimicrobial result.

RISK TO HEALTH

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

We believe the clinical risk is very low for the following reasons.

- Each individual cartridge is correctly labelled and readily identifiable before use.
- Each individual disc of each cartridge is printed with the correct ID and readily identifiable at point of use.
- Customer in-house laboratory quality control before testing on clinical samples would identify the error.

ACTIONS TO BE TAKEN

Our records indicate that you have received the above product.

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 amend your records accordingly.

The Medicines and Healthcare products Regulatory Agency (MHRA) has 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