

8th November 2018

URGENT FIELD SAFETY NOTICE

ThermoScientific™ Oxoid™ Brilliance VRE Agar

PO1175A Lot 2404072 Exp. Date 01 Nov. 2018

DESCRIPTION

Customers are to be advised of the following:

A technical investigation has confirmed that Thermo Scientific™ Oxoid™ Brilliance VRE Agar PO1175A Lot 2404072 may not recover Vancomycin-resistant *Enterococcus faecium*.

RISK OF USE

Thermo Scientific™ Oxoid™ Brilliance VRE Agar is a chromogenic screening plate for the detection of Vancomycin Resistant Enterococci (VRE). This medium provides presumptive identification of resistant *Enterococcus faecium* and *Enterococcus faecalis* directly from clinical samples within 24 hours.

Use of this batch may result in the failure to detect Vancomycin-resistant *Enterococcus faecium* from clinical samples. Testing has shown that Vancomycin-resistant *Enterococcus faecalis* continues to grow within expected parameters.

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 review your records. Requirement for review of reported test results should be determined by the appropriate technical expert.

The Medicines and Healthcare products Regulatory Agency MHRA will be informed of this Field Safety Corrective Action.

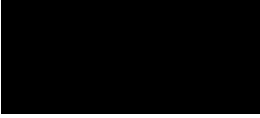
This notice needs to be passed on to all who need to be aware within your organisation or to any organisation where the potentially affected lots have been transferred.

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.

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

8th November 2018

ACKNOWLEDGEMENT FORM

URGENT FIELD SAFETY NOTICE

Re. ThermoScientific™ Oxoid™ Brilliance VRE Agar, PO1175A, Lot 2404072 Exp. Date 01 Nov.2018

Dear Customer,
(cc Chairman Medical Board and relevant Head of Departments)

Thermo Fisher Scientific, Microbiology, are requesting for customers to be advised of the following:

A technical investigation has confirmed that Thermo Scientific™ Oxoid™ Brilliance VRE Agar PO1175A Lot 2404072 may not recovery Vancomycin-resistant *Enterococcus faecium*, manufactured and sold between August – September 2018.

Please find enclosed a copy of the Field Safety Notice (F.S.N.) relating to this product for full details.

Accordingly, in keeping with our Quality Policy, we request that you review your records. Requirement for review of reported test results should be determined by the appropriate technical expert.

To meet regulatory requirements of the IVD Directive, I would be grateful if you would confirm receipt of this letter and F.S.N by emailing back a completed, signed copy of this Acknowledgement Form to the Customer Services Department on Fax no. +44(0)1256 479525 by 6th December 2018.

If you require any Technical Assistance please contact our Technical Support Team on 01256 694238 or at microbiology.techsupport.uk@thermofisher.com. Any other assistance, please contact your Customer Services Representative on **Contact No.**

Yours sincerely,

Signed :
Title :
Company :

CONFIRMATION OF RECEIPT

Thermo Fisher Scientific, Microbiology, FSN for ThermoScientific™ Oxoid™ Brilliance VRE Agar, PO1175A, Lot 2404072 Exp. Date 01 Nov. 2018

I confirm receipt of the F.S.N. for ThermoScientific™ Oxoid™ Brilliance VRE Agar, PO1175A, Lot 2404072 Exp. Date 01 Nov. 2018, dated 8th November 2018

Signed..... [redacted] ... Name (please print) [redacted] Position [redacted]

Date [redacted] Email Address/Telephone [redacted]