

05 DECEMBER 2018

**URGENT FIELD SAFETY NOTICE**  
**BRILLIANCE ESBL/BRILLIANCE CRE BIPLATE**  
**PO1265E Lot 2442472 Exp. Date 15 Nov. 2018**

**DESCRIPTION**

Customers are to be advised of the following:

A technical investigation has confirmed that Thermo Scientific™ Brilliance™ ESBL/Brilliance™ CRE Bi-Plate PO1265E Lot 2442472 may grow carbapenem sensitive *Escherichia coli* on the CRE side of this product.

**RISK OF USE**

Thermo Scientific™ Brilliance™ ESBL/Brilliance™ CRE Bi-Plate is for;

CRE Agar is a chromogenic screening plate for the detection of carbapenem-resistant Enterobacteriaceae.

ESBL Agar is a selective medium for the screening of clinical samples for the presence of extended-spectrum beta-lactamase (ESBL) producing bacteria.

Use of this batch may have resulted in false positive results on the CRE agar with the potential to create additional testing to confirm a CRE unnecessarily.

**ACTIONS TO BE TAKEN**

Our records indicate that you have received the above product.

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.

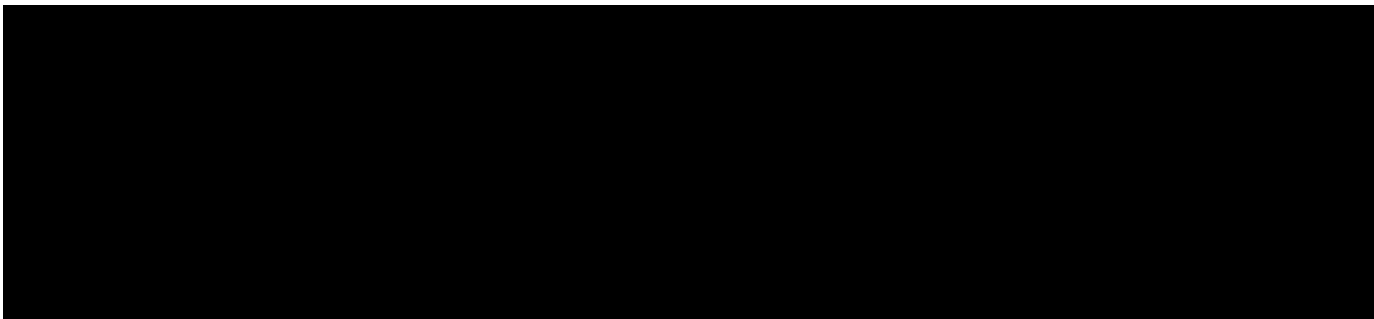
If you have any questions, please contact our Technical Support Department on

+44 (0)1256 694238, or at [microbiology.techsupport.uk@thermofisher.com](mailto: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,



14 January 2019

**ACKNOWLEDGEMENT FORM**

**URGENT FIELD SAFETY NOTICE**

**Re. Thermo Scientific™ Brilliance™ ESBL/Brilliance™ CRE Bi-Plate PO1265E Lot 2442472,**

**Exp. Date 15 Nov 2018**

Dear Customer,

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

A technical investigation has confirmed that Thermo Scientific™ Brilliance™ ESBL/Brilliance™ CRE Bi-Plate PO1265E Lot 2442472 may grow carbapenem sensitive *Escherichia coli* on the CRE side of this product.

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 5<sup>th</sup> January 2019.

If you require any Technical Assistance please contact our Technical Support Team on 01256 694238 or at [microbiology.techsupport.uk@thermofisher.com](mailto: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 Scientific™ Brilliance™ ESBL/Brilliance™ CRE Bi-Plate PO1265E Lot 2442472 Exp. Date 15 Nov 2018**

I confirm receipt of the F.S.N. for Thermo Scientific™ Brilliance™ ESBL/Brilliance™ CRE Bi-Plate PO1265E Lot 2442472 Exp. Date 15 Nov 2018, dated 5th December 2018.

Signed..... Name (please print)..... Position.....

Date..... Email Address/Telephone Number.....