

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.

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