

20th March 2019

URGENT FIELD SAFETY NOTICE

**ThermoScientific™ Oxoid™ Brilliance™ UTI Clarity Agar,
CM1106, lot no. 2465237, exp. 31-JAN-2024**

Customers are to be advised of the following:

DESCRIPTION

An internal technical investigation by Oxoid Limited, part of Thermo Fisher Scientific, has confirmed that *Escherichia coli* may grow as dark purple colonies on CM1106 Brilliance UTI Clarity Agar, lot 2465237 rather than pink as expected.

Continued use of this lot could result in the presumptive identification of *E. coli* colonies as a non-*E.coli* coliform which give a similar dark blue/purple colour reaction, e.g. *Citrobacter freundii*.

RISK TO HEALTH

Brilliance UTI Clarity Agar is used for the differentiation and presumptive identification of common urinary tract infection isolates. Any isolates appearing with a dark purple colour reaction should be further tested to determine identification.

As identifications are presumptive and further tests are required to confirm the identity of the isolate, we believe that there would be no delay in identifying *E. coli*, and that the clinical risk associated with this issue is low.

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 inventory of the lots listed above and contact Customer Services or your local distributor regarding any necessary replacements. Requirement for review of reported test results should be determined by the appropriate technical expert.

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 Acknowledgement 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



20th March 2019

ACKNOWLEDGEMENT FORM

Re. ThermoScientific™ Oxoid™ Brilliance™ UTI Clarity Agar, CM1106, lot no. 2465237, exp. 31-JAN-2024

Dear Customer,

Thermo Fisher Scientific, Microbiology, has taken the decision to recall ThermoScientific™ Oxoid™ Brilliance™ UTI Clarity Agar, CM1106, 2465237 sold in January 2019.

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 destroy any remaining inventory of the lots listed above and contact Customer Services or your local distributor regarding any necessary replacements. 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 17 APR-2019.

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

I confirm receipt of the F.S.N. for ThermoScientific™ Oxoid™ Brilliance™ UTI Clarity Agar, CM1106, 2465237, dated 20th March 2019.

I confirm that the product has been destroyed. **Please confirm No. of units destroyed.....**

I require replacement packs/Credit to be issued (Please indicate if none required) (send to Customer services department if required.)

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

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