

12th March 2019

URGENT FIELD SAFETY NOTICE

ThermoScientific™ Oxoid™ Brilliance Staph 24 Agar

P01186A Lot 2581635 Exp. 6th March 2019

DESCRIPTION

Customers are to be advised of the following:

A technical investigation has confirmed that Thermo Scientific™ Brilliance Staph 24 Agar, P01186A Lot 2581635 Expiry 6th March 2019, may exhibit low recovery of some *Staphylococcus aureus* strains.

RISK OF USE

Brilliance Staph 24 Agar is a selective, chromogenic medium for the isolation and enumeration of coagulase-positive staphylococci in foods and clinical samples.

There are no long term consequences from use of this lot of Brilliance Staph 24. The immediate clinical risk due to the failure to grow *S. aureus* from an infected site may be a delay in appropriate therapy for the infection when this is the only medium used. The majority of site infections will be empirically treated with broad spectrum antimicrobials to cover for *S. aureus*, but less than effective empiric treatment of a staphylococcal bacteraemia may result in delays in recovery, leading to requirements for further blood cultures or changes in treatment.

The clinical risk in these situations should be considered moderate to high. In the clinical laboratory, a non-selective medium (e.g. blood agar) should be used in conjunction with the chromogenic medium to ensure that the infecting isolate is not missed. Such routine practices will serve to mitigate the clinical risk and should only result in minor delays in reporting a presumptive *S. aureus* result.

ACTIONS TO BE TAKEN

Our records indicate that you have received the above product.

Accordingly, in keeping with our Quality Policy, we request that the 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 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

12th March 2019

ACKNOWLEDGEMENT FORM

URGENT FIELD SAFETY NOTICE

Re. ThermoScientific™ Oxoid™ Brilliance Staph 24 Agar, P01186A Lot 2581635 Exp. 6th March 2019

Dear Customer,

Thermo Fisher Scientific, Microbiology, has taken the decision to recall ThermoScientific™ Oxoid™ Brilliance Staph 24 Agar, P01186A Lot 2581635, manufactured and sold between January 2019 – February 2019.

Accordingly, in keeping with our Quality Policy, we request that the 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 9th April 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 Staph 24 Agar, P01186A Lot 2581635 Exp. 6th March 2019, dated 12th March 2019.

Signed..... Name (please print)..... Position.....
Date..... Email Address/Telephone Number.....