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01 December 2017

RE: Field Safety Notice – Thermo Scientific™ Oxoid™ Brilliance™ Staph 24

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

Please be informed of the product recall for the batches below.

1. Item(s) affected
Product: Brilliance Staph 24, PO1186A
Affected Lots: 2008685

2. Reason for notice
A technical investigation has confirmed that Thermo Scientific™ Oxoid™ Brilliance™ Staph 24 Agar PO1186A Lot 2008685 may not perform to the expected specification. Coagulase positive staphylococci (CPS) should grow as blue colonies on this medium however this for this lot, CPS colonies may appear white.
Continued use of this lot could results in false negative reporting for coagulase positive staphylococci.

Please refer to Field Safety Notice for full details.

3. Actions to be taken
- Discontinue the use and destroy any remaining inventory of the affected lots
- Kindly fill up the acknowledgement section below and send back to us.

Please refer to attached memo for more information and feel free to contact us should you have any queries regarding this notice.

Thank you for your prompt attention.

Yours Sincerely,

[redacted]

Ji Wenxin
Tel: 6499 9992
Email: wenxin.ji@thermofisher.com

Acknowledgement *(To be completed by end-user customer)*

I confirm receipt of the F.S.N. for Thermo Scientific™ Oxoid™ Brilliance™ Staph 24, PO1186A, dated 30th November 2017.

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)

Signed.....

Name (please print).....

Position.....

Date.....

Email Address/Telephone Number.....

Company Name & Stamp: .....

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30th November 2017

URGENT FIELD SAFETY NOTICE

Thermo Scientific™Oxoid™ Brilliance™ Staph 24
PO1186A Lot 2008685 D.O.M. 1st November 2017

DESCRIPTION

Customers are to be advised of the following:

A technical investigation has confirmed that Thermo Scientific™ Oxoid™ *Brilliance*™ Staph 24 Agar PO1186A Lot 2008685 may not perform to the expected specification. Coagulase positive staphylococci (CPS) should grow as blue colonies on this medium however this for this lot, CPS colonies may appear white.

Continued use of this lot could results in false negative reporting for coagulase positive staphylococci.

RISK TO HEALTH

Brilliance Staph 24 Agar is a selective, chromogenic medium for the isolation and enumeration of coagulase positive staphylococci (CPS) in clinical and food samples.

The primary concern is the potential for the medium to provide incorrect diagnostic morphology (blue colonies) for the organism under test. This may result in a delay in obtaining a valid test result or a failure to identify and report *Staphylococcus aureus* strains including Methicillin Resistant Staphylococcus Aureus (MRSA). The majority of clinical laboratories who take this medium will use it as a patient screening test for MRSA colonisation but some may also utilise it for clinical specimens, especially in patients who have previously had MRSA isolated.

The result of a failure of the medium when used for screening purposes maybe a delay in the identification of a *S. aureus* or MRSA carrier. This may have an impact on healthcare facility isolation/segregation practices raising the potential for cross colonisation of patients. If Brilliance Staph 24 Agar is the only medium used for this purpose then the clinical risk is potentially moderate to significant.

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From a clinical specimen perspective, the result of a failure of the medium maybe a delay in identifying the presence of *S. aureus* or MRSA with the potential for delays in treatment decisions. The majority of laboratories, however, will use also other culture media (e.g. Blood agar etc.), to identify infectious bacteria so a *S. aureus* isolate should be identified in a timely manner. The clinical risk in that setting should be low to moderate.

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 inventory, destroy this lot 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 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,

[redacted]

James H Filer
Vice President, Quality and Regulatory MBD