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URGENT FIELD SAFETY NOTICE

Thermo Scientific™ Oxoid™ *Brilliance*™ Salmonella Agar Base, CM1092B&T
Lots: 2113980; 2113981; 2114481; 2125747; 2125748

Customers are to be advised of the following:

DESCRIPTION

A technical investigation has confirmed that Thermo Scientific™ Oxoid™ *Brilliance*™ Salmonella Agar Base, CM1092B&T, Lots 2113980; 2113981; 2114481; 2125747 and 2125748 are not performing to specification.

The lots listed above are failing to meet the inhibition specification for the Quality Control organism *Escherichia coli* ATCC®25922™ i.e. 2 log inhibition. Continued use of these lots could result in a failure to identify *Salmonella* spp. if the tested sample also contains high levels of *E.coli*. A failure to inhibit the growth of *E.coli* could result in over growth masking the presence of Salmonella isolates.

Note
1) All lots support the growth of *Salmonella* spp. to the required specification.
2) Not all *E.coli* species are impacted and acceptable inhibition was observed with some strains.

RISK TO HEALTH

Brilliance™ Salmonella Agar Base is used to produce a selective medium for the presumptive identification and differentiation of *Salmonella* species. If the presence of Salmonella in a clinical sample was not identified then there is a risk of delayed diagnosis and delayed public health notification.

We believe the clinical risk associated with this issue is low to moderate for the following reasons:

- Direct plating methods by streaking should result in clearly identifiable single colonies.
- Selective enrichment may reduce the risk of competitive flora impacting on Salmonella recovery.
- Customer quality control procedures should identify the issue.
- Salmonella infections are not routinely treated with antimicrobial agents.

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) have 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.

We appreciate your immediate attention to this matter and apologise for any inconvenience this may have caused.

Yours sincerely,

[redacted]