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29th April 2016

URGENT FIELD SAFETY NOTICE

Oxoid Microbact Haemolysin Reagent, MB1249A Lot 1378446 D.O.M: 09/01/2016

Customers are to be advised of the following:

DESCRIPTION
A technical investigation has indicated that Microbact Haemolysin Reagent MB1249A lot 1378446 may not react strongly with all strains of *Listeria monocytogenes* when used in the Microbact Listeria 12L Kit (MB1128A), thus making interpretation of the result more difficult than with alternate batches.

Continued use of this lot may lead to failure to identify *L.monocytogenes.*

RISK TO HEALTH
The Microbact Listeria 12L system is intended to be used for the identification of *Listeria* spp. isolated from clinical, food and food related samples. Organisms should be gram positive bacilli, catalase positive and oxidase negative. This organism is found primarily in neonatal meningitis, so rapid presumptive identification is essential to provide direction for therapy.

For clinical applications the Microbact test should not be used in isolation or relied on solely to identify isolates as *L. monocytogenes*. Additional rapid methods such as haemolysis on blood agar, gram smear, and wet mount motility would be carried out immediately. In addition, other methods such as biochemical tests, PCR, etc would be included to confirm the identity. In a clinical setting the false negative found with a Microbact 12L test would, therefore, likely be identified as anomalous.

Not all strains of *L.monocytogenes* are affected by this issue and a number of specific strains tested during the investigation reacted correctly.

For the reasons given above we believe the clinical risk of a false negative result should be considered as low.

ACTIONS TO BE TAKEN
Our records indicate that you have received the above product.

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Accordingly, in keeping with our Quality Policy, we request that you destroy any remaining inventory of the lot 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.

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.

The Medicines and Healthcare products Regulatory Agency (MHRA) have been informed of this Field Safety Corrective Action.

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