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24 Jun 2016

URGENT FIELD SAFETY NOTICE

ThermoScientific™ Oxoid™ GC Agar, CM0367 (B,R,T,Q),

Lot 1671603 D.O.M 06.05.2015
Lot 1686234 D.O.M. 26.05.2015
Lot 1716560 D.O.M. 24.07.2015
Lot 1745003 D.O.M. 21.09.2015

Customers are to be advised of the following:

DESCRIPTION

An internal technical investigation has identified that Oxoid GC Agar, CM0367 (B,R,T,Q), lots 1671603, 1686234, 1716560 and 1745003, may not be providing acceptable microbiological performance when supplemented with Vitox (product code SR0090) alone in accordance with CLSI method M02-A11.

Continued use of these lots, when tested in accordance with the CLSI method, may result in a failure to support the growth of *Neisseria gonorrhoea* and may lead to delayed results reporting.

The performance of these lots remains unaffected when used with haemoglobin and other blood supplements.

RISK TO HEALTH

This product is made available for the isolation and further testing of pathogenic Neisseria species

The primary clinical concern is a potential delay in treatment of a gonococcal infection due to the lack of bacterial growth on the antimicrobial sensitivity test plate, resulting in a failure to report test results. There are two mitigating factors.

Most initial laboratory diagnosis of gonorrhoea is now done by NAAT testing (along with Chlamydia trachomatis – so called CT/GC testing). There are standard regimens for therapy that are administered prior to results of any culture and susceptibility analysis that may be performed. Antimicrobial susceptibility testing is done both for surveillance purposes, and to identify patients who may have acquired a resistant strain and in whom primary treatment has failed.

Primary quality control of GC media is typically a requirement for all new lots of media received in a laboratory before clinical testing is performed. In these circumstances the issue would be discovered before any clinical isolates were investigated.

For these reasons we believe the clinical risk is low.

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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 discontinue the use of these lots for applications requiring Vitox supplement 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 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