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URGENT FIELD SAFETY NOTICE

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

Customers are to be advised of the following:

DESCRIPTION

This notification is to inform customers of a change to the performance claim for Oxoid GC Agar (CM0367). We can no longer support the use of Oxoid GC Agar when supplemented only with Vitox (product code SR0090) in accordance with CLSI method M02-A11.

An internal technical investigation has identified that Oxoid GC Agar, CM0367, may provide variable microbiological performance when supplemented with Vitox only, resulting in poor growth of specific organisms i.e. *Neisseria gonorrhoea*. Continued use of this product when tested in accordance with the CLSI method may result in a failure to achieve a successful test outcome and could lead to delayed results reporting.

Oxoid GC agar performance remains unaffected when used in any other formulation and the product will continue to be made available for these applications.

We are actively investigating this issue, however the complex nature of the product means that identifying the root cause and finding a solution may take up to 6 months. We will update you periodically as to the progress of this work.

RISK TO HEALTH

This product, when supplemented with Vitox, 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.

1. 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.

2. 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.

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 this product for applications requiring Vitox supplement only and amend your records accordingly. This product can continue to be used for all other applications. Please 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 product has 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.

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