

7th July 2016

URGENT FIELD SAFETY NOTICE

ThermoScientific™ Oxoid™ Columbia Blood Agar Base CM0331 (B,R,S,T,U)

**Lots: (manufactured and distributed between 24/03/16 and 30/06/16)
1857212; 1857213; 1857214; 1857215; 1872633; 1872634; 1872635; 1872637**

Customers are to be advised of the following:

DESCRIPTION

Customer quality notifications followed by an internal technical investigation has identified that Oxoid Columbia Blood Agar Base, CM0331 (B,R,S,T,U) (lots listed above) may not provide acceptable microbiological performance when supplemented with whole horse or sheep blood. Recovery is lower than typically expected and haemolysis may be reduced, atypical or absent.

Continued use of these lots may result in a failure to identify or confirm the presence of some target strains of bacteria. This has been confirmed in our laboratories with specific clinical strains of *Streptococcus pyogenes*. The product continues to perform correctly with the quality control strains detailed in the QC specification for this medium.

Investigations into other applications incorporating the affected lots of this medium are on-going. More information will be made available in the near future.

RISK TO HEALTH

This product is made available as a multi-purpose culture medium suitable for the cultivation of fastidious microbial species. Although certain diagnostic tests may be performed directly on this medium, biochemical and, if indicated, immunological testing using pure cultures is recommended for complete identification.

The primary clinical concern is the potential for false negative reporting as a result of a laboratory failing to identify a poor growing and/or atypical haemolytic isolate, from a clinical sample. The level of clinical risk is dependent on the site of infection with the greatest risks associated with misidentification of bacteria isolated from wounds, especially if *S. pyogenes* infection is suspected. A false negative result from a throat swab would be less problematic as most patients with streptococcal pharyngitis are treated empirically before culture results are known. In blood cultures a *S. pyogenes* would not likely be missed even if the haemolysis was poor on primary plates. A gram-positive coccus in chains from the original culture sample would be treated promptly before the sample was plated on agar for culture identification.

ACTIONS TO BE TAKEN

Our records indicate that you have received one or more lots of the above product.

Accordingly, in keeping with our Quality Policy, we request that you review your use of this product, inspect your stocks 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