

11th August 2016

URGENT FIELD SAFETY NOTICE

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

On 7th July 2016 ThermoFisher Scientific issued a Field Safety Notice regarding 8 lots of Oxoid Columbia Blood Agar Base (CM0331). Lots: 1857212; 1857213; 1857214; 1857215; 1872633; 1872634; 1872635; 1872637. Details of this FSN are as follows.

DESCRIPTION

Customer quality notifications followed by an internal technical investigation have 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.

The specific performance issue detailed above was limited to 8 lots of CM0331; however, additional investigations into selective formulations incorporating CM0331 have identified other performance issues encompassing an increased number of lots.

The total list of affected lots is as follows:

Lots: (manufactured and distributed between 24/03/16 and 30/06/16) 1841145, 1841146, 1841147, 1857212, 1857213, 1857214, 1857215, 1865310, 1865311, 1865312, 1865313, 1872633, 1872634, 1872635, 1872637, 1874679, 1874680, 1874881, 1880288, 1880289, 1882159, 1882160

DESCRIPTION

A 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 used in selective formulations targeting *Staphylococcus* and *Streptococcus* spp.

This was confirmed with the following formulations:

- Columbia CAP with sheep blood (10 mg/l colistin, 2 mg/l aztreonam and 5% sheep blood).
- Columbia CNA aesculin agar (SR0176G Modified CNA Selective Supplement, 1 g/l aesculin and 5% sheep blood).
- Columbia Agar plus 2% Salt.

These formulations continue to perform correctly with the quality control strains detailed in the QC specification however; performance with some clinical strains may be atypical. Continued use of these lots, therefore, may result in a failure to identify or confirm the presence of some target strains of bacteria leading to incorrect or delayed, results reporting.

The investigations to date have confirmed acceptable performance when used in the following formulations. Please note that not all formulations have been tested and investigations are on-going.

Formulation	Blood	Selective Supplement
Columbia chocolate horse blood agar	10% Horse blood	N/A
Columbia chocolate horse blood agar with bacitracin	10% Horse blood	0.175 g/l Bacitracin
Gardnerella selective agar with sheep blood	5% Sheep blood	SR0119E
Helicobacter pylori selective agar	5% Lysed horse blood	SR0147E
Haemophilus blood agar	5% Horse blood	1.24 mg/l Haemin 1 mg/l Menadione sodium bisulphite 0.012 g/l Nicotinamide adenine dinucleotide
Columbia blood agar with gentamicin	5% Horse blood	5 mg/l Gentamicin
Columbia Blood agar with neomycin	5% Horse blood	75 mg/l Neomycin
Campylobacter Butzler medium	7% Sheep blood	SR0232E SR0085E
Campylobacter Skirrow selective medium	7% Lysed horse blood	SR0069E

RISK TO HEALTH

- 1) Columbia CAP with sheep blood (10 mg/l colistin, 2 mg/l aztreonam and 5% sheep blood). This formulation is a selective medium for the isolation and presumptive identification of Gram-positive bacteria from clinical specimens. The CM0331 lots listed above, when used in this formulation and for this application are displaying weaker growth and haemolysis with *Streptococcus* spp. *Staphylococcus* spp. tested are displaying acceptable growth and haemolysis. The primary clinical concern is the potential for false negative reporting of *Streptococcus* spp. as a result of a laboratory failing to identify a poor growing and/or atypical haemolytic isolate, from a clinical sample.
- 2) Columbia CNA aesculin agar (SR0176G Modified CNA Selective Supplement, 1 g/l aesculin and 5% sheep blood). This formulation is a selective medium for the isolation and presumptive identification of Gram-positive bacteria from clinical specimens. The CM0331 lots listed above, when used in this formulation and for this

application, are displaying weaker growth and haemolysis with *Streptococcus* spp. *Staphylococcus* spp. tested are displaying acceptable growth and haemolysis. The primary clinical concern is the potential for false negative reporting of *Streptococcus* spp. as a result of a laboratory failing to identify a poor growing and/or atypical haemolytic isolate, from a clinical sample.

- 3) Columbia Agar plus 2% Salt. This formulation can be utilised in combination with Oxacillin, for the antibiotic susceptibility testing of methicillin resistance in *Staphylococcus aureus* isolates. The CM0331 lots listed above, when used in this formulation and for this application, are producing larger than expected zones of inhibition. The primary clinical concern, therefore, is the potential for false sensitivity reporting and subsequent impact on therapeutic decisions.

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