

17th September 2019

FIELD SAFETY NOTICE

**ThermoScientific™ Oxoid™ Violet Red Bile Glucose Agar (ISO),
CM1082, lot no. 2507209, exp. 30-APR-2024**

Customers are to be advised of the following:

DESCRIPTION

An internal technical investigation by Oxoid Limited, part of Thermo Fisher Scientific, has confirmed that CM1082 Violet Red Bile Glucose Agar, lot 2507209 is not homogeneous.

Samples of the medium have been found to have pH values outside of specification and colour variation in both the dehydrated and reconstituted medium. This may be apparent when the medium is prepared. The recovery of in-house quality control strains was within specification however colony colour and size were variable and dependent on the sample of medium.

RISK TO HEALTH

Violet Red Bile Glucose Agar is used for the detection and enumeration of Enterobacteriaceae in food, animal feed and environmental samples. Any isolates appearing within a colour range of pink to purple may be counted however some strains may produce atypical colonies.

As identifications are for detection and enumeration only, we believe there would be no delay to confirmation of results, and that the risk associated with this issue is low.

ACTIONS TO BE TAKEN

Our records indicate that you have received the above product.

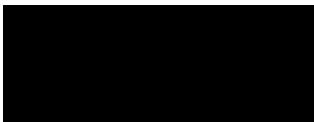
Accordingly, in keeping with our Quality Policy, we request that you destroy any remaining inventory of the lots listed above and contact Customer Services or your local distributor regarding any necessary replacements. Requirement for review of reported test results should be determined by the appropriate 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.

You should complete the accompanying Acknowledgement 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

17th September 2019

ACKNOWLEDGEMENT FORM

**Re. ThermoScientific™ Oxoid™ Violet Red Bile Glucose Agar (ISO),
CM1082, lot no. 2507209, exp. 30-APR-2024**

Dear Customer,

Thermo Fisher Scientific, Microbiology, has taken the decision to recall ThermoScientific™ Oxoid™ CM1082 Violet Red Bile Glucose Agar, lot 2507209 sold in May 2019.

Please find enclosed a copy of the Field Safety Notice (F.S.N.) relating to this product for full details.

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

I would be grateful if you would confirm receipt of this letter and F.S.N by emailing back a completed, signed copy of this Acknowledgement Form to the Customer Services Department on Fax no. +44(0)1256 479525 **by 15th October 2019.**

If you require any Technical Assistance please contact our Technical Support Team on 01256 694238 or at microbiology.techsupport.uk@thermofisher.com. Any other assistance, please contact your Customer Services Representative on **Contact No.**

Yours sincerely,

Signed :
Title :
Company :

CONFIRMATION OF RECEIPT

Thermo Fisher Scientific, Microbiology, FSN for Violet Red Bile Glucose Agar (ISO), CM1082, 2507209

I confirm receipt of the F.S.N. for ThermoScientific™ Oxoid™ CM1082 Violet Red Bile Glucose Agar, 2507209 dated 17th September 2019.

I confirm that the product has been destroyed. **Please confirm No. of units destroyed.....**

I require replacement packs/Credit to be issued (Please indicate if none required) (send to Customer services department if required.)

Signed..... Name (please print)..... Position.....

Date..... Email Address/Telephone Number.....