

1st August 2019

URGENT FIELD SAFETY NOTICE

Thermo Scientific™ Oxoid™ Staphylect Plus

Product Code	Kit Lot Number
DR0850M	2462081 Exp: Jun-2020

Description

Customers are to be advised of the following:

An internal technical investigation has determined that Thermo Scientific™ Oxoid™ Staphylect Plus (DR0850M) may show granularity before the recommended read end time. This granularity may be misinterpreted as a positive result when used according to the Instructions For Use.

Risk to Health

Thermo Scientific™ Oxoid™ Staphylect Plus (DR0850M) is intended for the differentiation of *Staphylococcus aureus* by detection of clumping factor, Protein A and certain polysaccharides found in methicillin resistant *S. aureus* (MRSA) from those staphylococci that do not possess these properties.

It has been concluded that the clinical risk is moderate based on the following rationale:

The clinical consequence of a false positive result could potentially result in unwarranted antimicrobial therapy and a potential delay in getting the correct therapy.

Action 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 Staphylect Plus (DR0850M), Lot 2462081.

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 product has been transferred.

The Medicines and Healthcare products Regulatory Agency (MHRA) have been informed of this Field Safety Corrective Action.

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,

A handwritten signature in blue ink, appearing to read 'James H Filer'.

James H Filer
Vice President, Quality and Regulatory
Microbiology Products

1st August 2019

ACKNOWLEDGEMENT FORM

Re. ThermoScientific™ Oxoid™ Staphylect Plus

Dear Customer,

Thermo Fisher Scientific, Microbiology, has taken the decision to recall ThermoScientific™ Oxoid™, Staphylect Plus, manufactured and sold between May 2019-July 2019.

To meet regulatory requirements of the IVD Directive, I would be grateful if you would confirm receipt of this Customer Notification by emailing a completed, signed copy of this Acknowledgement Form to the new vigilance email, mbd.vigilance@thermofisher.com, or Customer Services Department at Fax no. +44(0)1256 479525 by 29th August 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

I confirm receipt of the F.S.N. for ThermoScientific™ Oxoid™ Staphylect Plus, dated 1st August 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)

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

Position..... Date.....

Email Address/Telephone Number.....