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Urgent Field Safety Notice

Ref: DCCV-NC00695

Date: 09/11/2018 Attention Customers

Details on Affected Device:

Product Description	ThermoScientific™ Oxoid™ Brilliance VRE Agar
Product Code	PO1175A (W12500)
Lot Number	2404072
Expiry Date	01/11/2018

Description of the issue:

A technical investigation performed by Thermo Scientific™ Oxoid™ has confirmed that Brilliance VRE Agar PO1175A (W12500) Lot 2404072 may not recovery Vancomycin-resistant *Enterococcus faecium*.

Thermo Scientific™ Oxoid™ Brilliance VRE Agar is a chromogenic screening plate for the detection of Vancomycin Resistant Enterococci (VRE). This medium provides presumptive identification of resistant *Enterococcus faecium* and *Enterococcus faecalis* directly from clinical samples within 24 hours.

Use of this batch may result in the failure to detect Vancomycin-resistant *Enterococcus faecium* from clinical samples. Testing has shown that Vancomycin-resistant *Enterococcus faecalis* continues to grow within expected parameters.

Actions to be taken by the user:

Our records confirm that you have received the above lot. Fannin Ltd. Galway request that:

- Review of reported test results should be determined by the appropriate technical expert.

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action (if appropriate).

Contact Reference Person:

Irene Slevin

Fannin Ltd. Galway

IDA Industrial Estate

Galway

Email: Irene.slevin@fannin.eu

Tel: 00 353 1 290 7209

The undersign confirms that this notice has been notified to the appropriate Regulatory Authority.

A handwritten signature in blue ink, appearing to read 'Irene Slevin', with a stylized flourish at the end.