



Fannin Ltd.
Fannin House, South County Business Park,
Leopardstown, Dublin 18.
Tel: + 353 (01) 2907000
Fax: + 353 (01) 2907118
www.fannin.ie



Fannin Ltd.
I.D.A. Industrial Estate,
Ballybrit Upper, Galway.
Tel: + 353 (01) 2907204
Fax: + 353 (091) 771187
www.lipdiagnostic.com

Urgent Field Safety Notice

Date: 23/07/2018

W11103 Brilliance UTI Clarity Agar

1664711330 Exp. 2018/05/17
1665723330 Exp. 2018/05/25
1663730830 Exp. 2018/05/30
1664745825 Exp. 2018/06/07
1662764832 Exp. 2018/06/19
1663778430 Exp. 2018/06/27
1662788132 Exp. 2018/07/03
1663801332 Exp. 2018/07/11
1663823430 Exp. 2018/07/25
1663837032 Exp. 2018/08/01

ThermoScientific Oxoid, the manufacturer of the dehydrated culture media used in the manufacture of the lots listed above has issued an Urgent Field Safety Notice after an internal investigation confirmed that *Staphylococcus aureus* may grow as pink colonies on product manufactured using CM1106 Brilliance UTI Clarity Agar, lots 2299980 and 2300002. The expected colony colour is white/cream. The lots listed above were manufactured using CM1106 Brilliance UTI Clarity Agar, lot 2300002.

Continued use of these lots could result in the presumptive identification of *Staphylococcus aureus* colonies as *Escherichia coli* or *Staphylococcus saprophyticus*. Brilliance UTI Clarity Agar is used for the differentiation and presumptive identification of common urinary tract infections.

Prior to release of the lots listed above internal QC testing was carried out and results were within specification for productivity ratio and colony morphology.

Fannin Ltd Galway has issued this Field Safety Notice due to the low risk of delayed diagnosis, however, as confirmatory tests are required to confirm the identity of the organism there should be no delay in identifying *Staphylococcus aureus*. Requirement for review of reported test results should be determined by the appropriate technical expert. Any remaining stock of the lots listed above will be collected by Fannin Limited.

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.

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

The HPRA and MHRA have been notified



Irene Slevin

irene.slevin@fannin.eu

Tel: 01 290 7209