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Urgent Field Safety Notice

Ref: DCCV-CC00860

Date: 19/10/2018 Attention Customers

Details on Affected Devices:

Product Description	Brazier's CCEY Agar
Product Code	W11016
Lot Number	1813011141
Date of Manufacture	26/09/2018
Expiry Date	2018-11-07

Description of the issue:

Brazier's CCEY Agar is used for the isolation and presumptive identification of *Clostridium difficile* from clinical specimens. The morphology of *Clostridium difficile* is grey/white colonies.

Customers are advised that contamination has been reported in the above lot 20 days post-date of manufacture and is presenting as salmon/pink colonies.

Fannin Ltd. Galway is issuing this Field Safety Notice due to the risk that the contamination could interfere with the growth of the target organism and erroneous results could occur.

Identification is presumptive and confirmatory tests are required for final identification.

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.
- Any remaining stock should be destroyed and replacements will be supplied by Fannin Ltd. Galway.

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

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

