



Fannin Ltd
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Urgent Field Safety Notice

Date: 22/01/2019

Product Code & Name: W11064 X + V Agar

Lot Number: 0312142928

Expiry Date: 2019-02-05

Investigation Number: DCCV-CC00927

Details on affected devices:

W11064 X + V Agar, lot number 0312142928 is a medium used for the differentiation of *Haemophilus* species.

Description of the problem:

Customers are advised that contamination has been reported in the above lot 37 days post-date of manufacture and is presenting as cream/orange colonies. Fannin Ltd is issuing this Field Safety Notice due to the risk that the contamination could interfere with the detection of the presence or absence of growth in relation to the X, V and XV growth factor discs.

Advise on action to be taken by the user:

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

- A review of reported test results should be determined by the appropriate expert.
- Remaining stock should be destroyed and replacements will be supplied by Fannin Ltd.

Transmission of this Field Safety Notice

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:

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