



Fannin Ltd.
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Urgent Field Safety Notice

For Attention of Medical Scientists

Date:

06/05/2020

Product Code & Name: W11171 MUELLER HINTON AGAR + 5% BLOOD & NAD
(4mm)(EUCAST)

Lot Number: 1012943561

Investigation Number:
DCCV-NC01609 (FSN Ref)

Details on affected Devices:

Product description/commercial name	Product Code/Catalogue Number	Lot/Part Number	Date of Manufacture	Expiry Date	Device Type
MUELLER HINTON AGAR + 5% BLOOD & NAD (4mm)(EUCAST)	W11171	1012943561	21/04/2020	26/05/2020	IVD

Reason for Field Safety Notice

Description of the problem:

Customers are advised that contamination has been found during QC sterility testing in the above product lot.

Fannin Ltd Galway is issuing this Field Safety Corrective Action due to the risk that the contamination could interfere with the growth of the target micro-organism and give rise to erroneous results.

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

Primary clinical purpose of the device and hazard giving rise to the FSN:

W11171 MUELLER HINTON AGAR + 5% BLOOD & NAD (4mm)(EUCAST) is an antimicrobial susceptibility testing medium.

Type of Action to mitigate the risk

Advise on action to be taken by the user:

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

- Customer review all remaining stock and notify LIP of stock used to date/remaining stock
- Customer review reported test results – this should be determined by the appropriate technical expert.
- Customer allow Fannin Ltd Galway to collect any remaining stock. Replacements will be provided.

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 (of 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).

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

General Information

FSN Type: New

Further advice or information already expected in follow-up FSN: No

Contact reference person:

Helena Coughlan, Quality Assurance Manager

 6 MAY 2020

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**