

F-QA-00238 rev.16

Urgent Field Safety Notice

For Attention of Medical Scientists

Date: 24/08/2022**FSCA Identifier:** DCCV-NC03050**Product Code & Name:** W11074, GC Sensitivity Test Medium**Device Type:** Culture media Product (Agar)**FSN Type:** New**Is customer Reply Required?** Yes, immediately upon receipt of notification**Details on affected Devices:**

Lot number:	Date of Manufacture:	Expiry date:
107657	13/06/2022	01/08/2022
108103	11/07/2022	29/08/2022
108173	14/07/2022	01/09/2022
108253	21/07/2022	08/09/2022

Reason for Field Safety Notice**Description of the problem:**

Neisseria gonorrhoeae is failing to grow on the affected batches when performing Antimicrobial Susceptibility Testing (AST).

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

GC media is used to perform AST of *N. gonorrhoeae* and can be used for AST for other fastidious microorganisms. AST guides the clinician in the selection of the most appropriate antimicrobial treatment regimen. No growth on AST test media will result in repeat testing and a delay in reporting antibiotic profile results to the clinician managing patient treatment. This may result in a delay in patients being treated with the most appropriate antibiotic.

Type of Action to mitigate the risk**Advise on action to be taken by the user:**

- Discontinue use of Product W11074, GC Sensitivity Test Medium, batches listed above.
- Inspect stocks and update lipquality@fannin.eu of the remaining packs to be discarded.

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).

General Information**Further advice or information already expected in follow-up FSN:**

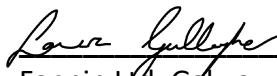
No.

If further advice or information is required, please email the contact reference below:

Contact reference person:

Dr Laura Gallagher

Quality Assurance Manager

 24/08/2022

Fannin Ltd. Galway

IDA Industrial Estate

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