

F-QA-00238 rev.16

Urgent Field Safety Notice

For Attention of Medical Scientists

Date: 27/10/2022 (Initial FSN issued 24/08/2022)**FSCA Identifier:** DCCV-NC03050**Product Code & Name:** W11074, GC Sensitivity Test Medium**Device Type:** Culture media Product (Agar)**FSN Type:** Update**Is customer Reply Required?** Yes**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).

Update:

Investigations to date has shown the issue of no growth of *Neisseria gonorrhoeae* on GC Sensitivity Test Medium is linked to a small number of clinical isolates which may signify a new variant(s). No issue has been identified with *N. gonorrhoeae* ATCC 49226. No direct link of isolate growth failures to the manufacturing process has been identified. Therefore, it is possible that a small number of clinical isolates will fail to grow on all future lots of GC Sensitivity Test Medium.

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.

Possible no growth of clinical isolates on this AST test media will result in test failure. Alternative genotypic tests may be utilised to determine genetic markers for antibiotic profile.

Type of Action to mitigate the risk

Action to be taken by the Manufacturer:

Fannin Ltd. (Galway) in communication with the HPRA, will re-supply product W11074, GC Sensitivity Test Medium to the marketplace to ensure continuity of AST testing of *N. gonorrhoeae* samples.

Fannin Ltd. (Galway) will continue to review data findings and provide an update to customers if additional information or alternative root cause is identified.

Fannin Ltd. (Galway) will review suitability of the product and liaise with raw material manufacturers and standard committees on this issue.

Advise on action to be taken by the user:

Please confirm receipt of this notification.

To be aware that a small number of clinical isolates of *N. gonorrhoeae* will fail to grow on all future lots of this test medium when in use. Where failures occur, alternative test methods should be utilised where possible.

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: Not planned

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

Contact reference person:

Dr Laura Gallagher

Quality Assurance Manager

 27/10/2022

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**