

F-QA-00238 rev.17

Urgent Field Safety Notice

For Attention of Medical Scientists

Date: 04/05/2023**FSCA Identifier:** DCCV-NC03525**Product Code & Name:** W11346 Fastidious Anaerobic Agar + Horse Blood**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:
111706	29/03/2023	10/05/2023
111675	28/03/2023	09/05/2023

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

Microbial contamination was identified in two batches of manufactured W11346 Fastidious Anaerobic Agar + Horse Blood.

Contamination is evident in packs of these batches remaining on site in the agar of the plates.

This type of contamination is uniform in appearance, presenting as small white/grey colonies with darkening of the surrounding media.

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

W11346 Fastidious Anaerobic Agar + Horse Blood is a primary isolation medium capable of growing most clinically significant anaerobes.

Contamination of the media not observed prior to use may result in repeat testing and would lead to a delay in reporting results.

This may also result in requiring a further sample from the patient e.g., a swab would become compromised if used on contaminated media.

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

Please inspect your stocks of W11346 batches 111706 and 111675 and update lipquality@fannin.eu to organise collection and replacement batch where required.

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 follow up FSN identified.

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

Contact reference person:

Gráinne O' Connor,
Senior Microbiologist.

Gráinne O' Connor 04/05/2023

Fannin Ltd. Galway

IDA Industrial Estate

Galway

Email: lipquality@fannin.eu

Tel: (01) 290 7208

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