

F-QA-00238 rev.17

Urgent Field Safety Notice

For Attention of Medical Scientists

Date: 19/06/2023**FSCA Identifier:** DCCV-NC03595**Product Code & Name:** W11050 Columbia Blood Agar**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:
112532	30/05/2023	04/07/2023

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

Microbial contamination was identified in W11050 Columbia Blood Agar Lot 112532.

Contamination is evident in packs of this batch in and on the agar surface of the plates. This type of contamination presents as white/cream circular colonies on the surface of the agar and cream circular/oval colonies in the agar.

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

W11050 Columbia Blood Agar is a highly nutritious multi-purpose medium suitable for the cultivation of fastidious organisms.

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 W11050 Lot 112532 and update lipquality@fannin.eu on 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 19/06/2023

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**