

Urgent Field Safety Notice

For Attention of Medical Scientists

Date:

28/08/2020

Product Code & Name: W11533 CHROMagar E.coli O157 + Cefixime/Tellurite

Lot Numbers: 1763074633, 1765961436, 1761878023

Investigation Number:

DCCV-NC01807 (FSN Ref)

Details on affected Devices:

Product description/commercial name	Product Code/Catalogue Number	Lot/Part Number	Date of Manufacture	Expiry Date	Device Type
CHROMagar E.coli O157 + Cefixime/Tellurite	W11533	1763074633	15/07/2020	09/09/2020	IVD
CHROMagar E.coli O157 + Cefixime/Tellurite	W11533	1765961436	01/05/2020	26/06/2020	IVD
CHROMagar E.coli O157 + Cefixime/Tellurite	W11533	1761878023	02/03/2020	27/04/2020	IVD

Reason for Field Safety Notice

Description of the problem:

Customers are advised that low-level fungal contamination has been observed in the above product lots.

Fannin Ltd Galway is issuing this Field Safety Notice 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:

W11533 is a selective medium for the isolation, differentiation and presumptive identification of Escherichia coli O157:H7 from food, veterinary and environmental sources.

The contamination as purple/mauve colonies at 48 hours with appearance of mycelium occurring after additional incubation up to 120 hours. As such, the contamination could potentially be misdiagnosed as the target microorganism and erroneous results could occur or the growth may be identified as suspicious at 48 hours and the test plate re-incubated and microorganism subsequently identified as non-target.

Most persons infected with E.coli O157:H7 recover within 5-10 days without any specific treatment plan. As such, there are minimal immediate health consequences as a consequence of misdiagnosis or delayed diagnosis in the absence of secondary complications.

Treatment of E. coli H157:O7 infection, where required, is administration of clear fluids to prevent dehydration. As such, there is minimal risk of an adverse reaction as a consequence of a false positive test result or delay in patient diagnosis.

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 discard 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.

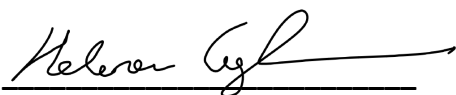
General Information

FSN Type: New

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

Contact reference person:

Helena Coughlan, Quality Assurance Manager



28/08/2020

Fannin Ltd. Galway

IDA Industrial Estate

Galway

Email: lipquality@fannin.eu

Tel: 00 353 1 2907204

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