



Fannin Ltd.
Fannin House, South County Business Park,
Leopardstown, Dublin 18.
Tel: + 353 (01) 2907000
Fax: + 353 (01) 2907118
www.fannin.ie



Fannin Ltd.
I.D.A. Industrial Estate,
Ballybrit Upper, Galway.
Tel: + 353 (01) 2907204
Fax: + 353 (091) 771187
www.lipdiagnostic.com

Urgent Field Safety Notice

Ref: DCCV-NC00788

Date: 19/02/2019 Attention Customers

Details on Affected Devices:

Product Description	Dermatophyte Test Medium (DTC-25)
Product Code	W11214
Lot Number	1841075428
Date of Manufacture	05/11/2018
Expiry Date	2019-03-05

Description of the issue:

Dermatophyte Test Medium (DTC-25) is used for the detection of dermatophytic fungi. This medium helps in the differentiation between saprophytic and environmental fungi.

Customers are advised that contamination has been found in inventory stock in the above lot 88 days post-date of manufacture.

Fannin Ltd Galway is issuing this Field Safety Notice due to the risk that the contamination could interfere with the growth of the target organism and erroneous results could occur. Identification is presumptive and confirmatory tests are required for final identification.

Actions to be taken by the user:

Our records confirm that you have received the above lot. Fannin Ltd. Galway request that:

- Review of reported test results should be determined by the appropriate technical expert.
- Any remaining stock will be collected by Fannin Ltd and replacements will be supplied.

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).

Contact Reference Person:



Irene Slevin

Fannin Ltd. Galway

IDA Industrial Estate

Galway

Email: Irene.slevin@fannin.eu

Tel: 00 353 1 290 7209

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