



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** **15<sup>th</sup> August 2016**

### **W11340 Streptococcus Medium**

**Lot No 0702551122 exp. 2016-08-02**

**Lot no 0705587160 exp. 2016-08-19**

Customers are advised that Fannin Ltd. is issuing a recall of the above defined culture media batches. This recall is a result of a Thermofisher Scientific recall notification for defined raw material (CM0331) lots.

Culture media batches manufactured by Fannin Ltd. (LIP site) passed quality control tests before release onto the market. There have not been any incidents reported to date with the use of these media batches. However, Thermofisher Scientific have identified possible reduced target organism recovery and/or atypical, absent or reduced haemolytic reactions when CM0331 is used to prepare selective media products targeting *Staphylococcus* and *Streptococcus* spp.

Please refer to Thermofisher Scientific FSN attached for specific details and further information resulting from their investigations to date.

Fannin Ltd. records confirm that your laboratory has received some of the LIP prepared W11340 Streptococcus Medium culture media batches defined above. We recommend a review of reported test results using the Fannin Ltd/LIP ten digit lot numbers (0702551122 & 0705587160) by your technical experts.

A review of current W11340 stock levels should also be undertaken, the attached Recall Confirmation Fax-Back completed and returned to LIP directly. Credit or replacements will be arranged as requested.

This notice needs to be passed onto all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The HPRA and MHRA have been notified of this FSN.

Please accept our apologies for any inconvenience this recall may cause. Should you require any further information please do not hesitate to contact me directly.

Best Regards,  
Eva Lyons  
QA Manager – LIP  
Eva.lyons@fannin.eu  
01-2907208