



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

Date: 23/03/2017

Product Code & Name: W14005 Selenite Broth 20ml

Lot Number: 0324008540

Date of Manufacture: 02/03/2017

Type of Action: Product Removal

LIP has observed colour variation in 7 out of 840 bottles of W14005 Selenite Broth 20ml, remaining in stock, lot number 0324008540 stored at temperatures <20°C. Selenite Broth normally presents as a clear liquid used as an enrichment medium for the isolation of Salmonella from faeces, urine, water, foods and other materials of sanitary importance. The colour variation in the 7 bottles is orange.

This colour variation was not observed in sterility samples incubated at 20-25°C for 139 +/-5 hours or in sterility samples incubated at 36-38°C for 91 +/- 5 hours.

Until identification can be carried out by an independent laboratory LIP has decided to issue this Field Safety Notice. The presence of Salmonella in Selenite Broth will cause a colour change from clear to orange; therefore, a false positive could result.

An internal investigation has been initiated to determine the cause of the colour variation and a report will be prepared to detail root cause and corrective actions.

Can you please dispose of all bottles on site and confirm this action has been completed with return of the attached Fax Back Form.

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. Please maintain awareness of this notice and the resulting action for an appropriate period to ensure effectiveness of the corrective action.

The HPRA have been notified

 23/3/2017

irene.slevin@fannin.eu

Tel: 01 290 7209