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Urgent Field Safety Notice

Date: 07/03/2018

Product Code & Name: Refer to attached product list

Lot Number: Refer to attached product list

Expiry Date: Refer to attached product list

Type of Action: Product Removal

Due to impending adverse weather conditions in Ireland expected 01/03/2018, a business decision was taken in Fannin L.I.P. that orders due for dispatch on 28/02/2018 for delivery to customers on 01/03/2018 would be dispatched on 27/02/2018 for delivery on 28/02/2018.

The courier Alltrans collected the consignment from Fannin L.I.P. on the evening of 27/02/2018 and it was brought to their Dublin depot, where it was sorted onto pallets and placed on trucks for delivery to customers on the morning of 28/02/2018.

However, due to earlier arrival of snow/ice conditions on the morning of 28/02/2018 the orders in the Dublin depot were unable to be delivered to customers on 28/02/2018.

The consignment was to be returned to Fannin L.I.P. on 05/03/2018; however, some orders were delivered to customers in error. As the product was stored outside recommended storage conditions for greater than 144 hours product efficacy could be impacted and expected growth promotion results not achieved.

Fannin L.I.P. has decided to issue this Field Safety Notice due to the possible risk of delayed/incorrect patient diagnosis if plates stored outside of recommended storage conditions for >144 hours were used.

Fannin L.I.P. will arrange for collection of unused packs on site and customer confirmation this action has been completed will be 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.

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The HPRA have been notified

Product Code	Product Description	Batch Number	Expiry Date
W14215	SELENITE CYSTEINE BROTH 9ml	0633642040	15-May-18
W11001	BACILLUS CEREUS AGAR	0613617734	28-Mar-18
W11023	PSEUDOMONAS ISOLATION MEDIUM	1113619323	11-Apr-18
W11000	BAIRD PARKER MEDIUM	0843652622	11-Apr-18
W11245	TRYPTONE SOY AGAR (Harmonised) 90mm Irradiated Single Wrap	0752639830	13-Jun-18
W11115	E.M.B.	0681624441	09-Apr-18
W11050	COLUMBIA BLOOD AGAR	0032652225	27-Mar-18
W11060	COLUMBIA CHOCOLATE AGAR	0043654760	11-Apr-18
W11200	McCONKEY AGAR w/o SALT	0084655825	12-Apr-18
W11246	TRYPTONE SOY AGAR (Harmonised) 90mm Irradiated Double Wrap	0754643130	19-Aug-18
W11251	TRYPTONE SOY AGAR (Harmonised) 55mm Irradiated Double Wrap	0753488625	14-May-18
W11050	COLUMBIA BLOOD AGAR	0033654630	28-Mar-18
W11496	BRILLIANCE MRSA II AGAR	1554655730	05-Apr-18
W11153	MUELLER HINTON II AGAR 4mm	0991647232	16-Apr-18
W11200	McCONKEY AGAR w/o SALT	0084655825	12-Apr-18
W11325	STAPH/STREP AGAR	0595645227	26-Mar-18
W11534	CHROMagar Salmonella Plus	1784642533	29-Mar-18
W11380	X.L.D. AGAR	0095646233	30-Mar-18
W11562	CHROMagar msuperCARBA	1893653523	04-Apr-18
W11111	D.C.A.	0291647828	02-Apr-18
W11075	G.C. MEDIUM (N.Y.C.)	0484642323	05-Apr-18

Product Code	Product Description	Batch Number	Expiry Date
W11010	CAMPYLOBACTER MEDIUM (PRESTON)	0023652741	11-Apr-18
W11010	CAMPYLOBACTER MEDIUM (PRESTON)	0023627941	28-Mar-18
W11295	BRILLIANCE CANDIDA AGAR	1544643422	05-Apr-18
W11155	MUELLER HINTON + 2% SALT (4mm)	0992637922	10-Apr-18
W11159	MUELLER HINTON + 5% SHEEP BLOOD (4mm)	0273640823	21-Mar-18
W11130	D.S.T.	0073619434	04-Apr-18
W14270	BRAIN HEART INFUSION 10ml	0262449012	20-Aug-18
W14000	SELENITE BROTH 10ml	0323594940	17-May-18
W11505	CHROMAGAR STEC	1625623827	16-Mar-18
W11305	COLUMBIA BLOOD AGAR + NEOMYCIN	0114644860	22-Mar-18
W11050	COLUMBIA BLOOD AGAR	0032652225	27-Mar-18
W11495	CHROMOGENIC LISTERIA AGAR (ISO)	1881646823	02-Apr-18