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## **Urgent Field Safety Notice**

**Date: 03/05/2017**

**Product Code & Name: W11305 Columbia Blood Agar + Neomycin**

**Lot Number: 0111104160**

Slow growing bacterial contamination has been found in sterility samples stored at 20-25°C and 36-38°C after extended incubation. L.I.P. sterility incubation times are 120 hours at 20-25°C and 72 hours at 36-38°C. Contamination was observed in sterility samples after 187 +/- 5 hours incubation at both temperatures. The contamination presents as isolated yellow colonies and a sample will be sent to an independent laboratory for identification.

Columbia Blood Agar with Neomycin is a selective medium to encourage the growth of clostridia, an anaerobic organism which presents as opaque colonies with a halo.

No contamination was identified in:

- retention samples stored at 2-10°C
- samples taken from the remainder of the batch stored at 2-10°C
- growth promotion of test panel organisms incubated at 36-38°C for 18 hours.

Fannin LIP has decided to issue this Field Safety Notice due to the small risk contamination could interfere with growth of the target organisms if normal incubation periods were extended.

Can you please dispose of any unused packs on site and confirm this action has been completed with the 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 resulting action for an appropriate period to ensure effectiveness of the corrective action.

**The HPRA has been notified**

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