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Urgent Field Safety Notice

Date: 11/12/2017

Product Code & Name: W11159 Mueller Hinton + 5% Sheep Blood

Lot Number: 0272500123

Fannin L.I.P. has been informed that W11326 Staph/Strep Selective Agar Modified plates have been found in 2 packs of W11159 Mueller Hinton + 5% Sheep Blood (4mm).

The outer label states W11159 Mueller Hinton + 5% Sheep Blood (4mm), lot number 0272500123, however, W11326 Staph/Strep Selective Agar Modified plates, lot number 1282500034 were found inside 2 packs of the W11159 Mueller Hinton + 5% Sheep Blood (4mm), lot number 0272500123.

As both W11159 Mueller Hinton + 5% Sheep Blood (4mm) and W11326 Staph/Strep Selective Agar Modified contain blood the colour of both product types are similar and W11326 could be used inadvertently if the individual plate information is not confirmed before use.

W11159 Mueller Hinton + 5% Sheep Blood (4mm) is used for disc diffusion susceptibility testing of clinical isolates of *Streptococcus pneumoniae* and other *Streptococci* as standardized by the Clinical and Laboratory Standards Institute (CLSI).

W11326 Staph/Strep Selective Agar Modified is a selective medium for *Staphylococci* and *Streptococci*; however, as this medium is not 4mm in depth it will not support disc diffusion for susceptibility testing of *Streptococcus pneumoniae* and other *Streptococci* as standardized by the Clinical and Laboratory Standards Institute (CLSI).

Fannin L.I.P. has decided to issue this Field Safety Notice due to the possible risk of delayed patient diagnosis if incorrect plates are used for disc diffusion susceptibility testing. Fannin L.I.P. will arrange for collection of any unused packs on site and customer confirmation this action has been completed will be 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 have been notified.

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