

23 Aug 2019

**RE: Field Safety Notice – Choc II Agar PP1068P90 & Columbia CNA with Sheep Blood/Choc II PP2042SP**

Dear Customer,  
(cc Chairman Medical Board and Relevant Head of Departments)

Please be informed of the product recall for the batches below.

**1. Item(s) affected**

<b>Product code</b>	<b>Description</b>	<b>Batch</b>	<b>Expiry</b>
PP1068P90	CHOC II AGAR	2836254	11 Oct 2019
PP2042SP	COL CNA SHP BLD / CHOC II	2836266	20 Sep 2019

**2. Reason for notice**

Repeat testing has confirmed that the above Lots of Choc II Agar and Columbia CNA with Sheep Blood/ Choc II Agar Plates may contain microbial contamination.  
Please refer to Field Safety Notice for full details.

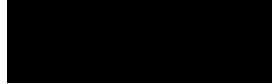
**3. Actions to be taken**

- Destroy any remaining inventory of the lot listed above.
- Review reported test results as necessary.
- Kindly fill up the acknowledgement section below and send back to us.

Please refer to attached memo for more information and feel free to contact us should you have any queries regarding this notice.

Thank you for your prompt attention.

Yours Sincerely,



Ji Wenxin  
Tel: 6499 9992  
Email:

**Acknowledgement** *(To be completed by end-user customer)*

I confirm receipt of the F.S.N. for Choc II Agar PP1068P90 lot 2836254 & Columbia CNA with Sheep Blood/Choc II PP2042SP lot 2836266, dated 23 Aug 2019.

I confirm that the product has been destroyed. **Please confirm No. of units destroyed.....**

I require ..... replacement packs/Credit to be issued (Please indicate if none required)

Signed.....Name (please print).....

Position.....

Date.....Email Address/Telephone Number.....

Company Name & Stamp: .....

23 August 2019

**URGENT FIELD SAFETY NOTICE**

**Choc II Agar PP1068P90 Lot 2836254 Exp. 11<sup>th</sup> Oct 2019**

**Columbia CNA with Sheep Blood Agar / Choc II PP2042SP Lot 2836266 Exp. 20<sup>th</sup> Sep 2019**

**DESCRIPTION**

Thermo Fisher Scientific advises that repeat testing has confirmed that the above Lots of Choc II Agar and Columbia CNA with Sheep Blood Agar Plates may contain microbial contamination.

**RISK OF USE**

Choc II Agar is for use in qualitative procedures for the isolation and cultivation of fastidious microorganisms, especially *Neisseria* and *Haemophilus* species, from a variety of clinical specimens.

Columbia CNA Agar with 5% Sheep Blood is a selective and differential medium used for the isolation and differentiation of gram-positive microorganisms from clinical and nonclinical materials.

There are no significant long term health consequences from use of these lots of agar plates.

The contamination should be readily identifiable prior to incubation, as such there is minimal risk the test may be invalidated due to contamination. Any immediate health consequence would be a potential delay in reporting test results if the plates were used.

**ACTIONS TAKEN**

These lots have been sent to four customers only within the Singapore Region.

In keeping with our Quality Policy, we are advising HSA prior to formally contacting customers to request a review of inventory and destruction of these lots.

Customers will be able to contact Customer Services or local distributor regarding any necessary replacements.

Please take this letter as official notification of Thermo Fisher request for a Field Safety Corrective Action.

The attached Customer notices will be provided to all of the four affected customers.

**INVESTIGATION & CORRECTIVE & PREVENTATIVE ACTIONS**

Under normal circumstances product still in retest would remain at the manufacturing site in Melaka Malaysia until release by Quality.

In these cases due to an urgent requirement products were transferred awaiting retest however were not restricted for sale from the Singapore warehouse. Immediately the results were known the lots were blocked however one and three orders respectively had been shipped to customers. This is a low level of contamination and as yet none of the customers have complained.

An immediate stop to pre shipping has been put in place with a thorough review of this practice to be undertaken by CAPA process.

The results of the recovery and final CAPA will be communicated to HSA at the required reporting intervals.

If there are any questions, please contact Ms Martini Hoan Senior Regulatory Manager Singapore  
[Martini.hoan@thermofisher.com](mailto:Martini.hoan@thermofisher.com)

On behalf of Thermo Fisher Scientific Malaysia & Singapore

***Leigh Willis***



Senior Quality Manager APAC

Microbiology

