

Urgent Field Safety Notice

Date: 02/12/2020

Product Code & Name: W14042 Chocolate Agar slopes

Lot Number: 0045232336

Investigation Number: DCCV-CC01507

Details on affected Devices:

W14042 Chocolate Agar slopes batch # 0045232336

Reason for Field Safety Notice

Description of the problem:

The Chocolate Agar Slopes W14042 were printed with a typographical error in the expiry date. The chocolate Agar bijou slopes, Batch # 0045232336 are printed with an expiry date and batch number onto the cap of each bijou. In this instance the individual bijous contain a typographical error in the expiry date. The date of 26/04/20 was printed on each cap instead of the correct date of 26/04/21, this product has a 6-month expiry and it was manufactured on the 23/10/20. The finished product pack is 50 bijous. A finished product label is placed onto the outer packaging. The correct date of expiry 26/04/21 was printed on the finished product label.

Primary clinical purpose of the device and hazard giving rise to the FSN:

The chocolate agar slopes are used to cultivate and maintain isolates to be re-examined or further characterized at a time after the culture was initially obtained and tested. They can also be used if isolates need to be sent to a national reference laboratory for confirmation of identity and/or further testing.

The incorrect expiry date printed on each bijou may result in a delay in the testing, disposal of the testing sample leading to not been able to test and a delay in the issuance of the reports of the testing.

Type of Action to mitigate the risk

Advise on action to be taken by the user:

- *Ensure this notification is readily available to all users of this product.*
- *The correct expiry date is 26/04/21 for each bijou.*
- *If you require to return or to dispose of this batch, replacement batches will be sent to you. Please send confirmation of this decision back to LIP, via the contact listed below and we will organise a collection and a replacement batch.*

Transmission of this Field Safety Notice

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 until the end of the expiry of this product to ensure effectiveness of this Field Safety Notice.

General Information

FSN Type:

Label issue – Typographical error on the internal expiry date printed on the bijou.

The undersign confirms that this notice has been notified to the appropriate Regulatory Authority.

If further advice or information is required, please email the contact reference below:

Contact reference person:

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Sinéad Donoghue 07th December 2020
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