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# Urgent Field Safety Notice

**Date: 08/01/2021**

**Product Code & Name:** W11171 MUELLER HINTON AGAR + 5% BLOOD & 20mg/L NAD (4mm) (EUCAST)

**Investigation Number:** DCCV-NC02007

**Attention: Medical Scientists**

**Details on affected Devices:**

The following lots have been identified as part of this FSN, the expiration date has superseded for all lots except for Lot: **1012329130 with an expiry on 02/02/2021**

**Lot Number:**

| | | |
|---|---|---|
| 1013258130 | 1012174830 | |
| **1012329130** | 1015250861 | |
| 1014309961 | 1012232630 | 1014158361 |
| 1014297730 | 1015220161 | 1011137830 |
| 1014285761 | 1013202130 | 1011119830 |
| 1014273661 | 1011184730 | 1012109625 |

## Reason for Field Safety Notice

**Description of the problem:**

The product W11171 MUELLER HINTON AGAR + 5% BLOOD & 20mg/L NAD was made using expired NAD with an expiry date of 09/08/2020, impacting 16 batches produced since 11/08/2020. The expired NAD may contribute to incorrect identification of pathogen sensitivity to an antibiotic.

The NAD supplement provides the V factor which is required for growth of fastidious Haemophilus species and other bacteria. Where the V factor is not available it can result in reduced or no bacterial growth.

This can delay in testing, reporting or effect the accuracy of AST as the growth-free zone are impacted.

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

Antimicrobial Susceptibility Testing (AST) is needed to predict how pathogens will respond to antimicrobials. This enables initiation of the most appropriate therapies as well as adapted measures to control the spread of infection.

W11171 MUELLER HINTON AGAR + 5% BLOOD & 20mg/L NAD (4mm) (EUCAST) Medium for antimicrobial susceptibility testing. Additional supplementation of the Mueller Hinton medium using 5% Horse Blood and 20mg/L of Nicotinamide adenine dinucleotide (NAD) makes it suitable for growth of fastidious organisms such as *Streptococcus pneumoniae* and *Haemophilus influenzae*. This is the required media following EUCAST (European Committee on Antimicrobial Susceptibility Testing) recommendations for AST.

## 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 product has passed all QC and additional testing to ensure product performance, no action is needed.*

- *If you require to return or to dispose of any batches, replacement batches will be sent to you. Please send confirmation of the 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:**
**FSN Notice – The supplement used in the manufacturing of W11171 had passed its expiration date.**

**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:**
*Sinead Donoghue*
*Quality Manager*
*Fannin Ltd*
*Ballybrit Industrial Estate,*
*Galway*
*H91FD9E*
*Sinead.Donoghue@fannin.eu*

Sinéad Donoghue 22nd January 2021
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