

Customer:
Axon Lab AG
Täferstraße 15
CH-5405 Baden-Dättwil

Hengersberg, 22.07.2022

Urgent safety measure

Product description: Müller-Hinton-Agar; REF: AL0901

Type of measure: Safety advice to the user to avoid the possibility of obtaining an incorrect result in terms of efficacy / resistance.

Issued by: Axon Biotech GmbH, D-Hengersberg
Axonbiotech Ref. No.: 2022-041

Dear Axonbiotech customer,

This letter is to inform you of a Field Safety Corrective Action (FSCA) affecting the product Müller-Hinton Agar, AL0901. Our records indicate that you have received one or more of the affected batches and are therefore subject to this safety-related action.

Description of the problem:

Müller-Hinton agar is a standard medium used for performing the Kirby-Bauer sensitivity test on fast-growing aerobic and facultative anaerobic microorganisms. The square-shaped plates make it possible to insert up to 16 antibiotic discs.

In the affected batches, there is a possibility that the inhibition zones of individual antibiotics are too small, which can lead to incorrect result regarding efficacy / resistance. As soon as this defect is detected during the incoming goods inspection, the batch must be blocked and no longer used in the practice.

Possible health risks:

With the affected batches, there is a possibility that the inhibition zones of individual antibiotics are too small, which can lead to a false result regarding efficacy /

resistance. Please check the validity of the test results and the measures taken that have been obtained with these batch numbers and discuss them with the laboratory manager or attending physician, if necessary.

Affected products:

AXL-I060-MH	AXL-I061-MH
AXL-I062-MH	AXL-I063-MH
AXL-I064-MH	AXL-I065-MH
AXL-I066-MH	AXL-I067-MH
AXL-I068-MH	AXL-I069-MH
AXL-I070-MH	AXL-I071-MH

Measures to be taken by the customer / user:

- Read this safety instruction carefully
- Notify all affected customers regarding this safety instruction
- Forward the enclosed reply to the affected clientele.
- Complete the enclosed response form immediately and return it to us by fax or e-mail as indicated on the form.
- Immediately block the affected batches
- Please keep this safety notice in a safe place.

Measures taken by the manufacturer:

- Replacement of the affected goods with a free replacement delivery or credit note.

Contact information:

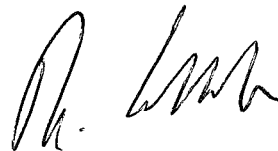
If you have any questions about this safety notice, please contact us at the following email address: info@axonbiotech.de.

The relevant national authorities have been informed of this safety measure.

We regret any inconvenience this may have caused. Please do not hesitate to contact us if you have any further questions.



Martina Deisinger
Quality Management Representative



Dr. Thomas Wolfrum
General Manager / Safety Officer



FAX - Reply form

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Im Oberfeld 2
DE-94491 Hengersberg

Fax-Number.: +49 9901 20 20 - 523
E-Mail: info@axonbiotech.de

Product: Müller-Hinton-Agar

REF: AL0901

LOT: AXL-I060-MH; AXL-I061-MH; AXL-I062-MH; AXL-I063-MH; AXL-I064-MH;
AXL-I065-MH; AXL-I066-MH; AXL-I067-MH; AXL-I068-MH; AXL-I069-MH;
AXL-I070-MH; AXL-I071-MH

☐ We have forwarded the safety information to all relevant users and can ensure that the products are used in accordance with this safety notice.

☐ We have returned affected products:

Quantity: _____

☐ We have destroyed affected products.

Quantity: _____

☐ Credit

☐ Replacement

☐ No affected products are available for return / destruction.

(Please fax or email this form back to Axonbiotech within 10 days)

Name of Facility: _____

Customer Number: _____

Date: _____

Name of contact person: _____

E-Mail: _____

Signature: _____