

Urgent Safety Information***Urgent Field Corrective Action (FSCA 04-2025)******B. subtilis inhibitor plate MiQ***

30.04.2025

Sender:

Axon Biotech GmbH
Im Oberfeld 2
94491 Hengersberg

Department: QM
Phone: + 49 – (0)9901 – 2029 – 0
Fax: + 49 – (0)9901 – 2029 – 73
E-mail: martina.deisinger@axonbiotech.de

Addressee**Distributor, user****Details on affected IVD product:**

B. subtilis inhibitor plate MiQ; REF: 510536

- MED-L027-BS
- MED-L028-BS

Description of the problem including the determined causes:

Dear customer,

In the case of batches MED-L027-BS and MED-L028-BS of the product B. subtilis inhibitor plate MiQ, we found that some of the plates were contaminated prematurely during internal testing over the runtime, making them unusable for further use.

The affected batches must be disposed of and not used for further tests.

There is no risk for the patient, user or third parties, as the plates are unusable before use due to contamination.

There is also no risk for the patient if the plates have already been used, as the results obtained with a non-contaminated plate correspond to the specification.

We are working to identify the cause, but the source of the error is not yet known. It may be due to the purchased spore solution.

What measures must be taken by the addressee?

The affected batches may no longer be used.

Please check your stocks immediately and dispose of the above-mentioned batches.

Passing on the information described here:

- Please discuss this letter with the person responsible in your company.
- If you have distributed the product that is the subject of this safety information to other customers, the customers concerned must be informed of this safety information immediately.
- Please keep this letter together with your laboratory records and forward it to others who may have received this product.
- The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".
- We kindly ask you to confirm receipt of this batch recall information using the enclosed fax reply by 09.05.2025. At the same time, please let us know whether you would like a replacement of the goods or a credit note.

Contact Person:

If you should have any questions regarding this information, please contact Mrs. Martina Deisinger at: +49 (0) 9901 – 2029 -12.

We apologize for any inconvenience caused and thank you for your reply.

Best regards,

Martina Deisinger, QMR
Axon Biotech GmbH

FAX - Reply

Axon Biotech GmbH
Im Oberfeld 2
94491 Hengersberg

Fax- No.: +49 (0) 9901 – 2029 – 73

E- Mail: info@axonbiotech.de

Product: B. subtilis inhibitor plate MiQ
Article.- No.: 510536
Batch: MED-L027-BS expiry date: 15.05.2025
MED-L028-BS expiry date: 17.05.2025

- ☐ I/we confirm receipt of this batch recall and forward it to all users of this product. **(Please mark with a cross and return to us by 09.05.2025).**
- ☐ Please send us a credit note for ____ Packs 510536
- ☐ Please replace ____ packs of 510536 free of charge.
- ☐ We do not require a credit note or replacement

Customer: _____

Customer number: _____

Date: _____

Name: _____

E- Mail: _____

Signature: _____