BÜHLMANN Laboratories AG
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Urgent Field Safety Notice (FSN-01166)

BÜHLMANN GanglioCombi® MAG ELISA Date: 01.03.2024

Changes in the ELISA plate assignment since Lot 3377N

Dear Customer, dear Distributor,

You are using our BÜHLMANN GanglioCombi® MAG ELISA kit.

Our records indicate that your facility received kits of one or more of the following products:

Product	Product reference code	Lot number	Expiration date
BÜHLMANN GanglioCombi® MAG ELISA	EK-GCM	3377N 3678N 4079.N	2025-02-28 2025-02-28 2025-04-30

Table 1. Concerned BÜHLMANN GanglioCombi® MAG ELISA product lots.

BÜHLMANNN Laboratories AG would like to inform you about a reported event where BÜHLMANN GanglioCombi® MAG ELISA was involved.

Description of the event and root cause:

Production batch 3377N is the first batch to leave our warehouse under the European legislation 2017/746 (IVDR) on IVD. At the same time as the IVDR changeover, changes were made to the ganglioside plate assignment based on feedback from the market: **Ganglioside GM2 was substituted with ganglioside GT1a** in all batches from this point onwards.

Remark: The last production batch numbers with GM2 under IVDD have been 2976, 2976.1 and lastly 2976.2.

All new IVDR kit batches (3377N, 3678N and 4079N) are accompanied by an information sheet that draws attention to the changes described in the instructions for use. In addition, distributors and sales partners have been made aware of this change by means of a corresponding marketing information dated 25. august 2023.

Unfortunately, we had to learn from a customer report from the Swiss market, that a user had overlooked this information. **This customer did not notice the change and therefore incorrect patient results were reported**.

Risk to health:

Incorrectly reported results that are misinterpreted as GM2 instead of GT1a can potentially lead to inappropriate treatment decisions for patients. However, these do not lead to a serious outcome as the first line treatment options are quite similar.

Advise on action to be taken by the Distributors:

- Identify and notify the users who received any of the new IVDR batches listed above batches and include a copy of this letter with the notification to users.

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- Identify and report number of users which have reported wrong results due to the change of the assay layout.
- complete the enclosed return form and confirm that you have received this notification and have completed the above steps.

Advise on action to be taken by the User:

- Check whether the information from the new instructions for use enclosed with the IVDR batches listed above has been received and implemented in your organization.
- Check that reported results generated with the concerned batches now reference GT1a and no longer GM2.
- If your organization has incorrectly reported GM2 instead of GT1a results, inform your client immediately and initiate measures in accordance with your internal guidelines.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the concerned products have been transferred. **It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN. Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.**

Please report any incidents related to the concerned product that result in a deterioration of a patient's health to the manufacturer (using the return form provided), the distributor and, if applicable, the competent national authority. The Competent (Regulatory) Authority of your country has been informed about this communication to Users.

BÜHLMANN sincerely apologizes for any inconvenience caused as a result of this Field Safety Notice. BÜHLMANN is committed to offering quality products and superior customer service. If you have any questions or comments arising from this Field Safety Notice, please contact:

Customer Support BÜHLMANN Laboratories AG

Ms. Charline Bubel, Mr. Anders Hansson
Email: support@buhlmannlabs.ch
Telephone: + 41 61 487 12 00

Best regards,

[redacted]
Quality Management Representative

[redacted]
VP Regulatory Affairs

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RETURN FORM – DISTRIBUTORS

Date: 01.03.2024

Please complete and promptly return by e-mail until 31.03.2024 to:

Customer Support BÜHLMANN Laboratories AG
support@buhlmannlabs.ch

Product	Product code	Batch number	Expiration date
BÜHLMANN GanglioCombi® MAG ELISA	EK-GCM	3377N 3678N 4079.N	2025-02-28 2025-02-28 2025-04-30

Type of Action:

Further to the enclosed Field Safety Notice, you are requested to complete the following:

- I have received and reviewed the enclosed Field Safety Notice. ☐ Yes / ☐ No
- I have informed all customers that have already received the above-mentioned products. ☐ Yes / ☐ No
- Did you get feedback from your customers, that wrong results have been reported and/or an incident was identified? ☐ Yes / ☐ No
- If Yes: How many of your customers gave feedback that they reported wrong results due to the change of the assay layout? # _____

Company Name:_____ Country: _____

Printed Name:_____ Signature: _____

Title: _____ Date (DD.MM.YYYY): _____

Email: _____ Phone: _____

Comments / Incidence identified (if any): .....

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Urgent Field Safety Notice (FSN-01166)

RETURN FORM – USER

Date: 01.03.2023

Please complete and promptly return by e-mail until 31.03.2024 to:

Customer Support BÜHLMANN Laboratories AG

support@buhlmannlabs.ch

Product	Product code	Batch number	Expiration date
BÜHLMANN GanglioCombi® MAG ELISA	EK-GCM	3377N 3678N 4079.N	2025-02-28 2025-02-28 2025-04-30

Type of Action:

Further to the enclosed Field Safety Notice, you are requested to complete the following:

1. I have received and reviewed the enclosed Field Safety Notice. ☐ Yes / ☐ No
2. I have checked that the information in the new instructions-for-use, enclosed with the concerned batches, has been implemented in my organization. ☐ Yes / ☐ No
3. I have checked that the reported results from the concerned batches now contain GT1a and no longer GM2. ☐ Yes / ☐ No
4. Did your organization incorrectly report GM2 instead of GT1a results? ☐ Yes / ☐ No

If (4) was answered with Yes:

5. The client was informed, and appropriate measures were taken in accordance with our internal guidelines. ☐ Yes / ☐ No

Company Name:_____ Country: _____

Printed Name:_____ Signature: _____

Title: _____ Date (DD.MM.YYYY): _____

Email: _____ Phone: _____

Comments / Incidence identified (if any):…… .

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