

Urgent Field Safety Notice (FSN 02.2019)

BÜHLMANN GanglioCombi™ MAG ELISA

Date: 17.09.2019

Potentially false negative results for BÜHLMANN GanglioCombi™ MAG ELISA

Dear Customer,

Our records indicate that your facility is using the following product:

Product	Product Code	Lot Number	Expiration date
BÜHLMANN GanglioCombi™ MAG ELISA	EK-GCM	2030	2020-10-31
		2030.1	2020-11-30
		2131	2020-11-30

Table 1. Affected BÜHLMANN GanglioCombi™ MAG ELISA product

The above mentioned lots of BÜHLMANN GanglioCombi™ MAG ELISA may generate false negative results, with Enzyme Labels IgG and IgG/IgM Mix.

Intended Use of BÜHLMANN GanglioCombi™ MAG ELISA:

BÜHLMANN GanglioCombi™ MAG ELISA, is an in vitro diagnostic test intended to detect auto-antibodies against defined relevant neural antigens/epitopes in serum samples from patients with suspected peripheral neuropathies with an unknown etiology. It allows quantitative classification of results into titre categories and serves as an aid to diagnosis of neuropathies.

Description of the issue:

Internal investigation, triggered by a customer complaint, showed false negative results for one positive internal control sample for the above-mentioned three lots of BÜHLMANN GanglioCombi™ MAG ELISA. BÜHLMANN has voluntarily initiated a Field Safety Notice. Corrective Actions (FSCA) for these lots. Investigations are still ongoing in order to identify the root cause.

Risk to Health:

The detected error may have led to false negative results. According to our risk analysis this may, in case of acute neuropathies (IgG-mediated), result in the incorrect assessment of disease prognosis and may lead to sub-optimal quality of follow-up healthcare e.g. prescribed physiotherapy. The error will also lead to incorrect information in the patients' health record that might decrease the quality of care.

Advice on action to be taken by the Distributors:

- Distributors have to discard / destroy any remaining stock of the above-mentioned lots.
- Distributors have to identify and notify Users who have received the aforementioned lots and provide a copy of this Field Safety Notice in your notification to your Users.
- Distributors have to provide BÜHLMANN with the list of affected Users.
- Distributors have to forward received and acknowledged Field Safety Notices from the Users by sending back the Users' Faxback Form.
- Distributors have to contact Customer Support and send request for the replacement of above-mentioned lots.
- Distributors have to complete the attached Faxback Form indicating that you have received this notification and acknowledge that you have accomplished the step indicated above.

Advice on action to be taken by the Users:

- As a precaution, please discard / destroy any remaining stock of the above-mentioned lots.
- Negative results generated using the above-mentioned lots with Enzyme Labels IgG and IgG/IgM Mix should be critically assessed in view of available clinical information. If necessary, retest the negative result(s) with new lots. Please perform further investigative procedures and pursue appropriate expert advice, if appropriate.
- For negative result(s) obtained with the above-mentioned lots, inform treating clinician about the possibility of a false negative result.
- Please contact your local supplier (distributor) and send request for the replacement of above-mentioned lots.

Action ongoing at BÜHLMANN:

- BÜHLMANN will replace above-mentioned lots of BÜHLMANN GanglioCombi™ MAG ELISA free of charge for the remaining inventory.
- BÜHLMANN has issued FSNs to all affected Users and initiated FSCA.
- Investigation is still on going at BÜHLMANN, in order to identify the root cause.

Transmission of this Field Safety Notice:

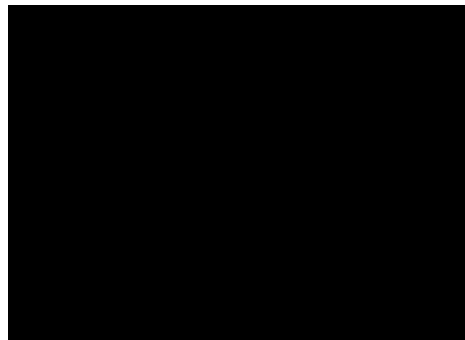
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected products have been transferred. Please maintain awareness of this notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related serious incidents, resulting in a deterioration to the patient's health, to the manufacturer (via the provided Faxback Form), distributor and the national Competent Authority if appropriate, as this provides important feedback. The Competent (Regulatory) Authority of your country has been informed about this communication to Users.

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
Email: support@buhlmannlabs.ch
Telephone: + 41 61 487 12 00

BÜHLMANN offers you our sincere apologies for the inconvenience caused as a result of this Field Safety Notice. Thank you for your trust and comprehension.

Best regards,



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FAXBACK FORM for Distributors

Date: 17.09.2019

Please complete and return by email until 15.11.2019 to:

Customer Support BÜHLMANN Laboratories AG
 Email: support@buhlmannlabs.ch

Product	Product Code	Lot Number	Expiration date
BÜHLMANN GanglioCombi™ MAG ELISA	EK-GCM	2030 2030.1 2131	2020-10-31 2020-11-30 2020-11-30

Type of Action:

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

Distributors:

- I have received and reviewed the enclosed Field Safety Notice and confirm this by returning the Faxback Form for Distributor. Yes / No
- I have discarded/destroyed any remaining stock of the aforementioned lots. (If yes, please specify the number below.) Yes / No
- I have forwarded the enclosed Field Safety Notice to the affected Users. Yes / No
- I have provided the list of affected Users. Yes / No
- I have returned the Faxback Form signed by the Users. Yes / No

Company Name: _____ Country: _____

Printed Name: _____ Signed: _____

Title: _____ Date: _____

Email: _____ Phone: _____

No. of kits destroyed: _____ No. of kits sold: _____

Comments:

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FAXBACK FORM for Users

Date: 17.09.2019

Please complete and return by email until 15.11.2019 to:

Customer Support BÜHLMANN Laboratories AG
 Email: support@buhlmannlabs.ch

Product	Product Code	Lot Number	Expiration date
BÜHLMANN GanglioCombi™ MAG ELISA	EK-GCM	2030 2030.1 2131	2020-10-31 2020-11-30 2020-11-30

Type of Action:

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

Users:

- I have discarded/destroyed any remaining stock of the aforementioned lots. (If yes, please specify the number below.) Yes / No

- I have assessed the negative result(s) generated by above lots of EK-GCM. Yes / No

- For negative result(s) generated by the above lots of EK-GCM, I have informed the treating clinician about the possibility of a false-negative result(s). Yes / No

- I have received information that deterioration in the state of health of a patient has occurred, possibly in connection to false negative result(s) generated by EK-GCM. (If yes, please specify in the comments below.) Yes / No

Company Name: _____ Country: _____

Printed Name: _____ Signed: _____

Title: _____ Date: _____

Email: _____ Phone: _____

No. of kits destroyed: _____ No. of kits used: _____

Comments:

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