

Field Safety Notice (FSN 02.2017)

BÜHLMANN GanglioCombi™ MAG ELISA
Enzyme-immunometric Assay Technique

Order code: EK-GCM

Affected lots: Lot # 0803

Expiry date: 2017-07-31

Date: 2017-02-14

Dear Distributor,

Our records indicate that you received the BÜHLMANN GanglioCombi™ MAG ELISA (order code: EK-GCM), Lot # 0803.

We hereby notify you that we received feedback from one customer concerning inter-lot inconsistencies involving the above mentioned kit lot # 0803. This could potentially lead to slightly different diagnostic outcomes. The variations observed at the client's laboratory were superior to the differences accepted by our quality control criteria. The discrepancies observed between the lots were sufficient to alter the diagnostic category of certain samples. Please note that the lot # 0803 passed the quality control and was therefore released.

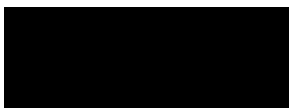
Concerning the clinical impact. Gangliosides demonstrating strong positivity remain consistent, thereby not altering the clinical information acquired. The reported discrepancies do not lead to any indirect harm, as the EK-GCM is intended to be used as an aid in the diagnosis of patients with a suspected auto-immune related peripheral neuropathy. Additionally BÜHLMANN only guarantees the validity of results if these were obtained by following the instructions for use mentioned within the kit. Solely serum samples can be confidently used for this assay.

To prevent any issues arising from the above mentioned discrepancies, we kindly ask you and the users to comply with the following:

- Verify operating procedures and correct any discrepancies with the official EK-GCM IFU.
- If any differences in the methodology are present, determine if there is a necessity to revue results obtained with the kit lot # 0803. Please do so according to your internal quality standards.
- Fill in the attached FAXBACK FORM and send it back to BÜHLMANN as rapidly as possible.

We sincerely apologize 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 our **Product Support** at: **support@buhlmannlabs.ch or by phone +41 61 487 1200.**

Best regards,


Marie-Christine Müller
Head Product Support
Fabio Perretta
QM Manager

Field Safety Notice

FAXBACK FORM

Date: 2017-02-14

Please complete and promptly return (by e-mail or Fax) to:*Fabio Perretta, Quality Manager Department, BÜHLMANN**Email: fp@buhlmannlabs.ch or Fax: + 41 61 487 12 34*

Affected products

Product	Catalog order code	Lot Number	Expiry date
BÜHLMANN GanglioCombi™ MAG ELISA	EK-GCM	0803	2017-07-31

Type of Action: Request above mentioned information from customer

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

Company Name: _____	Country: _____
Printed Name: _____	Signed: _____
Title: _____	Date: _____
Fax: _____	Phone: _____
Comments:.....	
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