BÜHLMANN Laboratories AG
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Urgent Field Safety Notice *(FSN 01.2018)*

BÜHLMANN IB*Doc*® Date: 2018-02-27

False negative result for IB*Doc*®

Dear Customer,

Our records indicate that:

- your facility received the following products:

Product	Product Code	Component	Lot Number
BÜHLMANN IB*Doc*®	LF-IBDOC8	CalApp® (Identifier: CALAPP)	Not applicable

Table 1. Affected IB*Doc*® product

- a failure in test result interpretation by the CalApp® software, for your patient(s) occurred.

Description of the issue: Last week an IB*Doc*® Account reported a case of a patient with confirmed clinical symptoms but a negative (<30 µg/g) IB*Doc*® result. BÜHLMANN immediately investigated this discrepancy and confirms a false negative result. The error occurred due to a limitation in the IB*Doc*® software. The result should have been indicated as “invalid”. With this finding, BÜHLMANN evaluated all raw data of all suspect results over the last 12 months and identified in total 13 incorrectly interpreted results.

Unfortunately, one of these results has been reported by your IB*Doc*® account:

Result ID:
Patient ID:
Date:

Result ID:
Patient ID:
Date:

Risk to Health: The detected error may have led to a false negative result. According to our risk analysis this may delay the appropriate treatment of your patient,

Advice on action to be taken: Please review the result(s) in question, disregard the result(s) from the patient’s result history (archive) and repeat a calprotectin measurement, if necessary. If appropriate, please perform further investigative procedures.

BÜHLMANN offers you our sincere apologies for the inconvenience and the resulting false results, which concerns about 0.2% of all reported results. Fixing the identified software limitation is our highest priority.

In the meantime, BÜHLMANN screens all suspect results on a daily basis in order to avoid new false negative case reports. We will inform you immediately if such a case should occur and your account is affected.

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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 other organisation where this software limitation occurred. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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

Ms Marie-Christine Müller or Ms Camilla Messerli
Email: support@buhlmannlabs.ch
Telephone: + 41 61 487 12 00

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.

Best regards,

Fabio Perretta
Head Quality Manager

Dr. Alicja Ritz
Head Regulatory Affairs

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Field Safety Notice *(FSN 01.2018)*

FAXBACK FORM

Date: 2018-02-26

Please complete and promptly return by email to:

Ms Marie-Christine Müller, Ms Camilla Messerli
Customer Support BÜHLMANN

Email: support@buhlmannlabs.ch

Product	Product Code	Component	Lot Number
BÜHLMANN IB*Doc*®	LF-IBDOC8	CalApp® (Identifier: CALAPP)	Not applicable

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 reviewed the above mentioned result(s) ☐ Yes / ☐ No
- I have noted deterioration in the state of health of my patient, possibly as a result of this failure. (If yes, please specify in the comments below.) ☐ Yes / ☐ No

Company Name:_____ Country: _____

Printed Name:_____ Signed: _____

Title: _____ Date:_____

Email: _____ Phone: _____

Comments: .....

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