BÜHLMANN Laboratories AG
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Urgent Field Safety Notice (FSN-00335)

Quantum Blue® Anti-Infliximab Date: 2022-01-12

Increased rate of false-positive results for production series 1107

Dear Customer, dear Distributor,

You are using our Quantum Blue® Anti-Infliximab assay in combination with the Quantum Blue® Reader.

Our records indicate that your facility received at least one kit of the following products:

Product	Catalog order code	Lot Number	Expiration date
Quantum Blue® Anti-Infliximab	LF-ADIF10 LF-ADIF25	1107.N.S 1107.N	30.04.2022

Table 1. Affected Quantum Blue® Anti-Infliximab production series

BÜHLMANNN Laboratories AG would like to inform you about a field safety corrective action regarding the Quantum Blue® Anti-Infliximab production series 1107.

Description of the issue and root cause: Positive, instead of negative, results have been reported by customers for the low control and patient samples for Quantum Blue® Anti-Infliximab production series 1107. The increased false-positive rate was confirmed internally at BÜHLMANN. Approximately 80% of low control results and 24% of negative patients' samples are now expected to be false positive.

The first observation of the low control measured as positive was made at a customer site on November 5th, 2021. Production series 1107 was released according to BÜHLMANN's quality control criteria, with the low control and negative internal control samples measured correctly as negative. Furthermore, internal measurements performed up to October 15th, 2021 confirmed that the low control, and negative patient samples, were correctly measured negative.

The observed unspecific positivity is caused by the reagent called Chase Buffer (Ref. Code: B-LFADIF-CB) used for the dilution of controls and samples. This reagent shows an instability over time for the Quantum Blue® Anti-Infliximab production series 1107 leading to false positive results.

Risk to Health: False positive results, incorrectly indicating high anti-infliximab antibody titers, may lead to inappropriate treatment decisions for patients with inflammatory bowel disease (IBD) and rheumatoid arthritis (RA) under infliximab therapy.

Advise on action to be taken by the Distributors:

- Please discard/destroy any remaining stock of the affected kit lots.
- Please identify and notify Users who have received the affected lots and provide a copy of this letter in the notification to your Users.

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- Please complete the attached Return Form indicating that you have received this notification and acknowledge that you have accomplished the steps indicated above.

Advise on action to be taken by the Users:

- Please discard/destroy any remaining stock of the affected kit lots. BÜHLMANN will replace remaining kits of production series 1107 with newly released kits.
- Please contact your local supplier (distributor) and, if needed, send a request for the replacement of the affected kits of production series 1107.
- BÜHLMANN recommends that you forward this letter to treating healthcare practitioners, in accordance with your organizations policy and any applicable country-specific guidance on patient management.
- BÜHLMANN recommends that positive test results obtained after October 15th, 2021 be repeated with newly released kits, in accordance with your organizations policy and any applicable country-specific guidance on patient management.

Action and resolution ongoing at BÜHLMANN:

- BÜHLMANN has issued Field Safety Notice to all affected Users and initiated Field Safety Corrective Action.
- BÜHLMANN will replace affected kits of BÜHLMANN Quantum Blue® Anti-Infliximab free of charge.
- BÜHLMANN has performed additional stability testing to ensure that newly released Quantum Blue® Anti-Infliximab production series maintains its performance until the expiration date.
- The newly released production series of the Quantum Blue® Anti-Infliximab will be continuously monitored for possible stability issues.

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 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 Return Form), distributor and the national Competent Authority, as appropriate, as this provides important feedback. The Competent (Regulatory) Authority of your country has been informed about this communication to Users.

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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

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

Best regards,

Fabio Perretta
Quality Management Representative

Michael Schneider
VP Regulatory Affairs

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Urgent Field Safety Notice (FSN-00335)

RETURN FORM – DISTRIBUTORS

Date: 2022-01-12

Please complete and promptly return by e-mail until 24.01.2022 to:

Customer Support BÜHLMANN Laboratories AG

support@buhlmannlabs.ch

Product	Catalog order code	Lot Number	Expiration date
Quantum Blue® Anti-Infliximab	LF-ADIF10 LF-ADIF25	1107.N.S 1107.N	30.04.2022

Type of Action:

Further to the enclosed Field Safety Notice, we ask that you 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
- I have discarded/destroyed any remaining stock of the afore mentioned lots. (Please specify the number of destroyed and sold kits, below.) ☐ Yes / ☐ No

Company Name:_____ Country:_____

Printed Name:_____ Signed: _____

Title: _____ Date: _____

Email: _____ Phone: _____

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

Comments/noted serious incidents (if any):.....

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Urgent Field Safety Notice (FSN-00335)

RETURN FORM – USERS

Date: 2022-01-12

Please complete and promptly return by e-mail until 24.01.2022 to:

Customer Support BÜHLMANN Laboratories AG

support@buhlmannlabs.ch

Product	Catalog order code	Lot Number	Expiration date
Quantum Blue® Anti-Infliximab	LF-ADIF10 LF-ADIF25	1107.N.S 1107.N	30.04.2022

Type of Action:

Further to the enclosed Field Safety Notice, we ask that you complete the following:

- I have received and reviewed the enclosed Field Safety Notice ☐ Yes / ☐ No
- I have discarded/destroyed any remaining stock of the aforementioned lots. (Please specify the number destroyed and used kits below). ☐ Yes / ☐ No

Organization: _____ Country: _____

Printed Name: _____ Signed: _____

Title: _____ Date: _____

Email: _____ Phone: _____

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

No. of kits needed for re-test and replacement of destroyed kits: _____

Comments/noted serious incidents (if any):……

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