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IBL International GmbH, Flughafenstraße 52a, 22335 Hamburg

Hamburg, 2017-11-21

Urgent Field Corrective Action RE51021 / MuSK-Ab ELISA / Lot EMU124

Dear Customer,

This notice is to inform you about a quality issue with IBL International's product RE51021 / MuSK-Ab ELISA / Lot EMU124 / Expiry date 2018-10-31.

Description of the problem:

The user of this assay may recognize that the antiserum (#KEMU521, lot: S882) and assay buffer (#KEMU751, lot: S881) appears contaminated (cloudy and contained particles). This issue is caused by a contamination of lot # EMU124.

IBL International received a complaint reporting this issue. IBL confirmed in our retain product that the contamination was observed; however, the lot met all manufacturing and QC criteria when it was originally released.

Risk assessment

Contaminated substances are visible and easily detected upon opening the kit. Instruction for use chapter (4) warning and precautions informs: In case of severe damage of the kit package please contact IBL or your supplier in written form, latest one week after receiving the kit. Do not use damaged components in test runs, but keep safe for complaint related issues.

The issue is detectable prior to use of the product. The performance of the kit is not affected by the contamination as demonstrated by internal testing of the contaminated retain kit. The performance data demonstrated that the controls remained within specification.

Action to be taken by distributors and end-users:

Please **immediately examine your stock** and/or **contact all customers that received the affected lot**. If you have any kits, **promptly quarantine these products**. Contact us with the quantity of the kits remaining, so that we can organize the replacement free of charge.

For our internal statistics please fill out and return the attached response form.

Patient samples that have been determined recently remain valid, if all criteria of the kit were met (standard curve plausible / controls met QC certificate acceptable ranges / no contamination recognized during test procedure).

With kind regards

IBL International GmbH

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Product Manager

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