



INTERNATIONAL

Empowered with Tecan ●

IBL International GmbH, Flughafenstraße 52a, 22335 Hamburg

Urgent
Field Safety Corrective Action
IBL International GmbH
EBV EA IgM ELISA, RE56231

Date: 2020-03-19

Dear Tecan IBL Customer,

This notice is to inform you about a quality issue with IBL International's product RE56231 / EBV EA IgM ELISA / Lot EAM-207 / Expiry date 2021-03-06.

Reason for Field Safety Corrective Action and Hazards Associated with the Failure

The user of this assay may recognize an increased optical density (OD) of single standards. The OD values obtained with the kit may be borderline or exceed what is stated on the QC certificate.

Investigation Results and Root Cause

IBL International received a complaint reporting this issue. IBL International confirmed in follow-up measurements that the calibration standards were partly found outside the specifications of the QC certificate; however, the lot met all manufacturing and QC criteria when it was originally released. IBL International initiated a root cause analysis which is currently ongoing.

Corrective Action/Required Action

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

Patient samples that have been determined recently remain valid, if all criteria of the kit, which are stated in the QC-certificate, were met.

We apologize for the inconvenience this has caused. If you have any questions regarding this communication or need assistance, please contact your local Tecan HelpDesk or IBL International directly; Tel. +49 (0) 40 53 28 91-0.

With kind regards

IBL International GmbH

IBL International GmbH

Flughafenstraße 52 a
D-22335 Hamburg
Tel. +49 (0) 40 53 28 91-0
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IBL@IBL-International.com
www.IBL-International.com

Geschäftsführer:
Geert W. Nygaard
Dr. Rudolf Eugster
Registergericht Hamburg
HRB 104008

Deutsche Bank
Account: 577 073 000
BLZ: 200 700 00
IBAN: DE91 2007 0000 0577 0730 00
BIC (Swift): DEUTDEHHXXX

Steuernummer: 49/733/00453
Umsatzsteuer ID: DE261098089



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RESPONSE FORM – EBV EA IgM ELISA, RE56231

To:	IBL International GmbH
Fax:	+49 (0) 40 53 28 91- 11
Email:	Constanze.Kallinich@tecan.com
Re:	Urgent Field Safety Corrective Action, March 2020

Customer name:	
Contact person:	
Phone number:	

Please check ALL appropriate box(es)

- ☐ I have read and understood the instructions in 'Urgent Field Safety Corrective Action, March 2020' letter.
- ☐ I have checked my stock and have _____ product(s) on hold that need to be replaced. I have scrapped the products on hold.
- ☐ I have informed my end-users of this Urgent Field Corrective Action

Please check ALL boxes to describe your business

- | | |
|--|---|
| <input type="checkbox"/> Wholesale / Distributor | <input type="checkbox"/> Re-packer |
| <input type="checkbox"/> Hospital / Medical Facility | <input type="checkbox"/> Medical Laboratory |
| <input type="checkbox"/> University Laboratory | <input type="checkbox"/> Research Institute |

Please confirm the quantity of kits remaining at your facility for which you would require replacement:

Product Description, Reference	Lot Number	Quantity of product on stock	Quantity of requested kits for replacement
EBV EA IGM ELISA, RE56231	EAM-207		

PLEASE RESPOND BY **April 10th, 2020.**

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