



INTERNATIONAL

Empowered with Tecan ●

IBL International GmbH, Flughafenstraße 52a, 22335 Hamburg

Hamburg, 2019-02-26

Field Corrective Action / Customer Notification

Echinococcus IgG ELISA, RE56201

Dear Customer,

This notice is to inform you about quality issue with IBL International's product Echinococcus IgG ELISA (product number: RE56201), lot EG-204, expiring 2020-02-14.

Description of the Problem and Hazards Associated with Failure:

IBL detected a degradation of the enzyme conjugate used in the Echinococcus IgG ELISA, RE56201, lot EG-204. This leads to overall lower optical density (OD) values; and the standard values are below the acceptable ranges stated on the Quality Control Certificate.

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

Investigation Results and Root Cause

A CAPA Investigation has been opened. The CAPA ensures corrective and preventive actions are implemented to prevent recurrence of the instability of the enzyme conjugate.

Risk to Health

The risk to health is considered to be negligible, as the results obtained with the kit cannot be released. The quality criteria for the runs are not met, the OD for the calibrators are below the acceptable range. The laboratory can immediately identify that the run is not valid.

Please follow your laboratory standard operational procedures to review any potential aberrant results that may have occurred.

Required Action to be taken by end-users:

Please **immediately examine your stock** and/or **contact all customers that received the affected lot**. If you have any kits with the above lot number, **promptly stop using and quarantine** these kits. Please enter the quantity quarantined on the attached response form. IBL is arranging for replacement product upon request.

Please contact IBL International by returning the enclosed response form by either fax or email as soon as possible, so that we can organize the replacement of Echinococcus IgG ELISA lot EG-204.

We apologize for this issue and if you have any questions, please contact IBL.

Kind regards,
IBL International GmbH

Anne Hartenhauer
Product Manager

IBL International GmbH

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Geschäftsführer:
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Registergericht Hamburg
HRB 104008

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

Steuernummer: 49/733/00453
Umsatzsteuer ID: DE261098089



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RESPONSE FORM – Echinococcus ELISA, RE56201

To:	IBL International GmbH
Fax:	+49 (0) 40 53 28 91- 11
Email:	anne.hartenhauer@tecan.com
Re:	Field Corrective Action / Customer Notification Echinococcus IgG ELISA

Customer name:	
Contact person:	
Phone number:	

Please check ALL appropriate box(es)

- I have read and understood the instructions in the notification letter of February 2019.
- 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
Echinococcus IgG ELISA, RE56201	EG-204 2020-02-14		

PLEASE RESPOND BY 29th MARCH, 2019 AT LATEST.

IBL International GmbH

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