

Hamburg, 2018-08-23

Field Corrective Action RE58731 / Taenia solium IgG ELISA

Dear Customer,

This notice is to inform you about an labelling error provided with the product Taenia solium IgG ELISA :

Catalogue-No.	Lot-No.	Expiry date
RE58371	TAEG-061	2019-09-30

Description of the Problem and Hazards Associated with Failure:

IBL detected an issue regarding the labelling of the negative control and cut-off control vials. The vial labels of the controls have been exchanged. This can be identified as the control bottles have different lid color codes, which are described in the Instructions for use (IFU).

Our records show that your laboratory received one or more kits from the affected lot.

As indicated in the instructions for use the negative control is having a blue colored bottle lid and the cut-off control is having a green colored bottle lid.

Investigation Results and Root Cause

A corrective and preventive action (CAPA) Investigation has been opened to ensure corrective and preventive actions are implemented to prevent recurrence. The root cause is due to an error during labelling of the single components of the product. The lid color on each vial is correct; however, the labels have been switched and are incorrect. IBL takes this issue very seriously and as a result is informing customers of the issue with the affected lot.

Risk to Health

The parasitic infection caused by Taenia solium is cysticercosis involve the eye and the central nervous system. The user can identify the incorrect labeling by comparing the information provided by IFU and current lid color and vial labeling before use. The failure will generate for every run invalid data, because the result for controls and cut-off should be compared to the provided lot specific data and criteria in the QC certificate and will not match or be valid and the results cannot be released.

According to the instructions for use, the diagnosis of an infectious disease should not be established on the basis of a single test result. A precise diagnosis should take into consideration clinical history, symptomatology as well as serological data. In immunocompromised patients and newborns serological data only have restricted value.

IBL International GmbH

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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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Required Action to be taken by end-users:

Please immediately examine your stock for the affected lot. If you have any kits with the above lot number, promptly add this letter informing about the mislabeling of negative control and cut-off control to the product. Reevaluate all prior data obtained with the concerned lot. Additional measurements are not required.

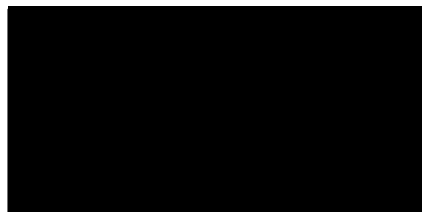
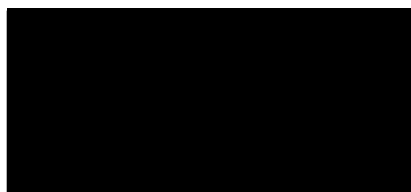
Please confirm the quantity of stock and the re-evaluation of any patient data from affected lot. If necessary affected products can be replaced.

Please contact IBL International by returning the enclosed response form by either fax or email as soon as possible for our records.

We apologize for this issue and if you have any questions, please contact your local Tecan Helpdesk or IBL.

With kind regards

IBL International GmbH



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IBL International GmbH, Flughafenstraße 52a, 22335 Hamburg

RESPONSE FORM – Taenia solium IgG ELISA

To:	IBL International GmbH
Fax:	+49 (0) 40 53 28 91- 39
Email:	Anne.hartenhauer@tecan.com
Re:	Field Corrective Action Taenia solium IgG ELISA

Customer name:	
Contact person:	
Phone number:	

Please check ALL appropriate box(es)

- ☐ I have read and understood the instructions in August 2018 letter.
- ☐ I have checked my stock and have _____ product(s) on hold and attached the FCA letter informing as correction about the mislabeling.
- ☐ I have informed my end-users of this 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:

Product Description, Reference	Lot Number	Quantity of corrected product on stock	Quantity of re-evaluated patient data
Taenia solium IgG ELISA, RE58731	TAEG-061		

PLEASE RESPOND BY SEPTEMBER 14th, 2018.

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