



INTERNATIONAL

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IBL International GmbH, Flughafenstraße 52a, 22335 Hamburg

Hamburg, 2019-02-11

## Field Corrective Action / Customer Notification

### DHEA ELISA, RE52221

Dear Customer,

This notice is to inform you about quality issue with IBL International's product DHEA ELISA (product number: RE52221), lot EDH118, expiring 2020-04-30.

#### Description of the Problem and Hazards Associated with Failure:

IBL detected a possible contamination (particles and discoloration) of the standards (#KEDH611, lot: R713A-2A) and controls (#KEDH651/KEDH661, lot: R714A-2A/ R715A-2A) used in the DHEA ELISA of lot EDH118. This leads to overall lower OD values; and the standard and control 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 contamination 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 standards and controls.

#### Risk to Health

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 affected by the contamination as demonstrated by internal testing of the contaminated retain kit. The performance data demonstrated that the controls remained outside specification, lead to invalid test runs.

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.

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

# IBL

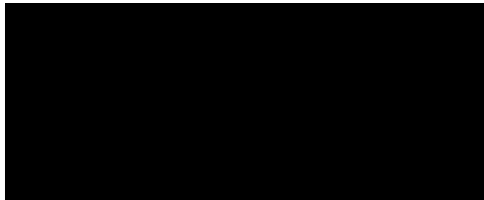
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Please contact IBL International by returning the enclosed response form by either fax or email as soon as possible, so that we can organize the replacement of DHEA ELISA lot EDH118.

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

Kind regards,  
IBL International GmbH



**IBL International GmbH**

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## RESPONSE FORM – DHEA ELISA, RE52221

To:	IBL International GmbH
Fax:	+49 (0) 40 53 28 91- 11
Email:	<a href="mailto:michael.sartor@tecan.com">michael.sartor@tecan.com</a>
Re:	Field Corrective Action / Customer Notification DHEA 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
DHEA ELISA, RE52221	EDH118		

PLEASE RESPOND BY 08<sup>th</sup> MARCH, 2019 AT LATEST.

#### IBL International GmbH

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