

# IBL

INTERNATIONAL

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IBL International GmbH, Flughafenstraße 52a, 22335 Hamburg

Hamburg, 2018-11-01

## Field Corrective Action / Customer Notification Androstenedione ELISA, DB52161

Dear Customer,

This notice is to inform you about a possible deviation in the results obtained with the product Androstenedione ELISA (product number: DB52161), lot 187000, expiring 2019-04-30 and lot 182140 expiring 2019-09-30.

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

IBL detected a degradation of the conjugate used in the Androstenedione ELISA of lot 187000 and lot 182140. This leads to overall lower OD values; and the standard values are below the acceptable ranges stated on the Quality Control Certificate.

### 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 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 for 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 Androstenedione ELISA.

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

With kind regards

IBL International GmbH

  
Magali Fischer  
Head of Global Reagent Marketing & Support

Kai Ohlroggen  
Head QM/RA



IBL International GmbH

Flughafenstraße 52 a  
D-22335 Hamburg  
Tel. +49 (0) 40 53 28 91-0  
Fax +49 (0) 40 53 28 91-11  
IBL@IBL-International.com  
[www.IBL-International.com](http://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 – Androstenedione ELISA, DB52161

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

Customer name:	
Contact person:	
Phone number:	

### Please check ALL appropriate box(es)

- I have read and understood the instructions in the Customer notification letter of September.
- 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

- Wholesale / Distributor
- Hospital / Medical Facility
- University Laboratory
- Re-packer
- Medical Laboratory
- 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
Androstenedione ELISA, DB52161	187000		
Androstenedione ELISA, DB52161	182140		

PLEASE RESPOND BY 10 November, 2018

IBL International GmbH

Flughafenstraße 52 a  
D-22335 Hamburg  
Tel. +49 (0) 40 53 28 91-0  
Fax +49 (0) 40 53 28 91-11  
[IBL@IBL-International.com](mailto:IBL@IBL-International.com)  
[www.IBL-International.com](http://www.IBL-International.com)

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