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IBL International GmbH, Flughafenstraße 52a, 22335 Hamburg

Hamburg, 2019-08-06

Field Corrective Action Estrone Saliva ELISA; RE52681

Dear Customer,

This notice is to inform you about a quality issue with IBL International's product Estrone Saliva ELISA (product number: RE52681), lot 98K019 and lot 98K019-2, both expiring, 2020-01-31.

Description of the Problem and Hazards Associated with Failure:

IBL detected an issue that indicates that the two lots may determine a higher percentage of samples with < 2.1 pg/mL for men and < 2.6 pg/mL for woman. Also saliva samples in the Normal Range Value of the kit were generally assayed significantly lower (approx. 50%). Therefore there is a possibility of inappropriate diagnosis. The issue is caused by a component of the calibrator's matrix that has lost activity over time which was not detected during our standardized production and QC process.

In case operators have used the kits of the affected lots, they may observe that:

- Optical densities (OD) of calibrators seem to be normal.
- Controls are in acceptance range.
- Patients sample concentrations are lower than expected.

Previous lots were checked and did not show this problem.

Investigation Results and Root Cause

A CAPA Investigation has been opened. The CAPA ensures corrective and preventive actions are implemented to prevent recurrence. Initial analysis shows a loss of activity by a component of the calibrator's matrix over time.

Risk to Health

The Salivary Estrone ELISA is an immune-diagnostic assay for the detection of Estrone in saliva. Estrone levels are measured as an aid in fertility studies in woman and to monitor Estrogen HRT (Hormon Replacement Therapy). Fertility problems and HRT are not diagnosed on the outcome of Estrone alone but accompanied by other diagnostic test such as Estradiol. Too low test results are associated with a medium to low risk. Either an unnecessary HRT with Estrogen in postmenopausal women could be applied, or an omitted therapy with antisteroids in women. The likelihood for occurrence of such a condition is very low, however because the error is discovered due to an increase of low values in the patient collective and due to conflicting clinical results: e.g. with Estradiol. The health risk for patients is minor in summary (temporal and

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

Required Action to be taken by end-users:

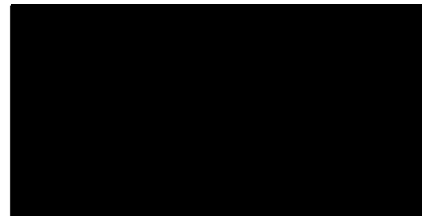
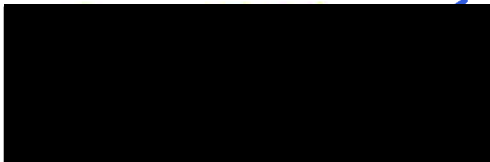
Please **immediately examine your stock** and/or **contact all customers that received the affected lots**. If you have any kits with the above lot number, **promptly stop using and quarantine** these kits. Please enter the quantity quarantined on the attached response form. IBL is arranging for replacement product upon request. Patient samples that have been determined with the affected lots should be checked again carefully. If results are lower than expected, samples should be re-run again.

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 Estrone Saliva ELISA lot 98K019 and lot 98K019-2.

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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RESPONSE FORM – Estrone Saliva ELISA, RE52681

To:	IBL International GmbH
Fax:	+49 (0) 40 53 28 91- 11
Email:	[REDACTED]
Re:	Field Safety Notification/ Customer Information Estrone Saliva ELISA

Customer name:	
Contact person:	
Phone number:	

Please check ALL appropriate box(es)

- I have read and understood the instructions in the customer letter (Estrone Saliva ELISA) of August 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
Estrone Saliva ELISA	98K019/ 98K019-2		

PLEASE RESPOND BY AUGUST 15th, 2019.

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