



INTERNATIONAL

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IBL International GmbH, Flughafenstraße 52a, 22335 Hamburg

Hamburg, 2018-01-12

Urgent Field Corrective Action

RE62111 / Cortisol Saliva LUM

RE62119 / Cortisol Saliva LUM

Dear Customer,

This notice is to inform you about a deviation of specification with specific lots of IBL International Cortisol Saliva Luminescence Immunoassay (LUM):

Reference	Lot Number	Expiry date
RE62111	LCL130	2018-03-31
RE62111	LCL134	2019-03-31
RE62119	LCL129	2017-11-30
RE62119	LCL131	2018-05-31
RE62119	LCL132	2018-10-31
RE62119	LCL133	2019-03-31

Description of the Problem and Hazards Associated with Failure:

IBL detected an issue that indicates a degradation in performance of the kit that results in elevated cortisol values. When testing patient samples with one of the affected lots, the controls and calibrator values will meet specifications; however, due to a degradation in the starting concentration of the calibration standards, the calculated results for individual patient samples may be higher compared to LC-MS/MS measurements and deviate from NIST standard calibration.

A summary of bias results versus the NIST Cortisol Standard is provided below ($r > 0.9$):

Reference	Lot Number	Bias
RE62111	LCL130	1.3x
RE62111	LCL134	1.7x
RE62119	LCL129	1.4x
RE62119	LCL131	1.5x
RE62119	LCL132	1.4x
RE62119	LCL133	1.5x

Our records indicate that your laboratory received one or more of the affected lots.

As indicated in the instructions for use of the kit, it is important that each laboratory establish reference ranges and develop internal quality control samples to assess each lot prior to use. Additionally, the results obtained using the kit should not be the sole determinate for diagnosis of adrenal disorders or changes to therapy.

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Deutsche Bank
Account: 577 073 000
BLZ: 200 700 00
IBAN: DE91 2007 0000 0577 0730 00
BIC (Swift): DEUTDE33HAN

Steuernummer: 49/733/00453
Umsatzsteuer ID: DE261098089



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Investigation Results and Root Cause

IBL detected this issue during a complaint investigation. The root cause is due to an error during production. A CAPA has been opened to ensure corrective and preventive actions are implemented to prevent recurrence. IBL takes it very seriously and as a result is informing customers of the issue with the affected lots.

Risk to Health

Since Cortisol is not used in isolation but is correlated with clinical history and presentation, as well as additional diagnostic laboratory testing, the health risk is minor. Please follow your laboratory standard operational procedures to review any potential aberrant results that may have occurred.

Required Action to be taken by distributors and end-users:

Please immediately examine your stock for the affected lots and contact all customers that received the affected lots and provide them with this Urgent Field Corrective Action. If you have any kits with the above lot numbers, 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.

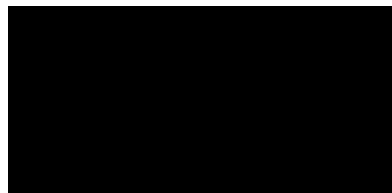
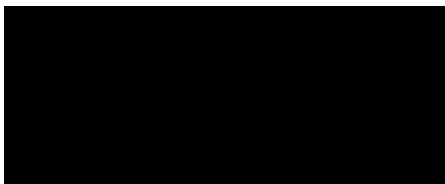
As above, please follow your laboratory standard operational procedures to review any potential aberrant results that may have occurred.

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 a new lot of Cortisol Saliva LUM free of charge. We expect to have a new lot of Cortisol Saliva LUM available to ship by the end of February 2018.

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

With kind regards

IBL International GmbH



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