



INTERNATIONAL

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IBL International GmbH, Flughafenstraße 52a, 22335 Hamburg

URGENT FIELD SAFETY NOTICE

Commercial name of product: Parathyroid hormone intact ELISA

Type of action: Field Safety Notice 27 October 2016

Attention: Customer(s)

Date: 27 October 2016

Dear Customer,

This field safety notice is to inform you of a potential issue the function of Calibrator A being reported from our kits made in year Q1 2016.

Details of affected devices:

The product list to this Field Safety Notice is the following:

Parathyroid hormone intact ELISA NM59041

Lot 2488 exp. 2017-02-28

Description of the problem:

Loss of separation between Calibrators A and B has been reported from Lot number 2488 of our Intact-PTH kits. The potential issue is associated with high background being observed for Calibrator A. Elevated optical density (OD 450 nm) of Calibrator A may cause loss of separation between Calibrators A and B, which may impact the assay calibration at the lower end of the assay. Based on initial patient sample testing, the loss of separation between Calibrators A and B does not lead to false results when our results are compared to other validated reference methods. Therefore, our current information demonstrates the assay is not reporting false results. We are investigating as quickly and diligently as possible to confirm this issue and determine root cause. As of this time, other lots have not been implicated; however, in the interest of safety, we are including the above lot in this notice.

Until such time as we can positively identify the root cause, we are notifying all of our customers and request that you report any analytical issues observed with lot 2488. As we continue our investigation into this issue, we will contact you with updates and additional specifics.

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Geschäftsführer:
Geert W. Nygaard
Registergericht Hamburg
HRB 104008

Deutsche Bank
Account: 577 073 000
BLZ: 200 700 00
IBAN: DE91 2007 0000 0577 0730 00
BIC (Swift): DEUTDE33

Steuernummer: 49/733/00453
Umsatzsteuer ID: DE261098089



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Hazard Analysis:

Potential Harm (erroneously low results at low end of curve): PTH results in the low

range can occur post-operatively after parathyroid removal. If the customer is using intact-PTH for post-operative monitoring and values appear to be erroneously low, the patient could be treated as though the parathyroidectomy was successful when it was not.

Potential Harm (erroneously normal results at high end of curve): PTH results that are >66.5 pg/mL (elevated outside the normal range) could run in the normal range. If elevated PTH results run erroneously within the normal range, the patient may be misdiagnosed as not having hypercalcemia of malignancy when the condition exists.

Potential Harm (delayed treatment): Delayed diagnosis and treatment may arise from an invalid assay run or unavailability (quarantining) of the product.

Actions to be taken by distributors and end-users:

Please immediately examine your stock and promptly quarantine the products with lot number 2488 and keep in quarantine until further notice. As part of the product investigation, the field safety corrective action for the product disposition will be determined based on the investigation outcome and regional requirements of the end-user site.

In addition, if you have further distributed the product(s) subject to this notice, please identify the customers and provide them with this Urgent Field Safety Notice. Please monitor and reconcile the quarantine of product with the customers as this information may need to be provided to the authorities. End users are instructed to run assays using an alternate method, therefore avoiding delayed treatment of the patient.

Please maintain awareness of this notice and resulting action(s) until further notice to ensure effectiveness of the Field Safety Corrective Action.

Please contact your local Customer Service or Sales Representative if you have any questions or concerns regarding this notification.

Please complete and return the enclosed response form by either fax or email as soon as possible, but not later than 04 November 2016.

The National Competent Authorities of all countries that the device was shipped to have been notified of the Field Safety Notice.

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Manufacturer Contact:

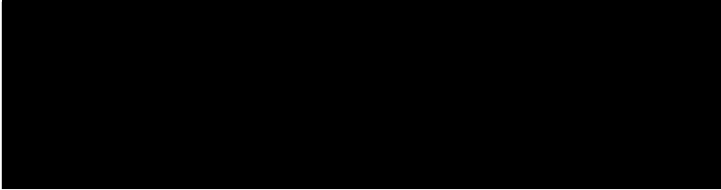
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Sincerely,



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