

Urgent Field Safety Notice

Commercial name of product: Calcitonin ELISA (NM59011)
Date: 24. September, 2014
Type of action: Customer information

Date: 24. September, 2014

Attention: Customers

Details on affected devices:

Lot 2041 exp. 2014-10-31;
Lot 2124 exp. 2015-03-31;
Lot 2178 exp. 2015-06-30.

Description of the problem:

Possibly false positive values have been reported from lot numbers 2041 and 2071 of the Calcitonin ELISA. As of this time it is not sure if other lots are impacted, however in the interest of safety, all the above listed lots are included in this notice. Significantly elevated Calcitonin levels are one possible indicator of the presence of C-cell hyperplasia or medullary thyroid cancer. However, Calcitonin levels are no longer used as a primary indicator of medullary cancer. Calcitonin values can be elevated in other conditions and should be interpreted in the context of other procedures, such as thyroid biopsy, scan, and ultrasound in order to establish the diagnosis. Until a root cause can positively identified we are notifying all our customers and request that you report any incidents and work with us to obtain information for investigation. As we continue our investigation in this issue, we will contact you with updates and additional specifics.

Advice on action to be taken by the distributors and end-users:

- Immediate examination of your stock and prompt quarantine of the products with the lot numbers 2041, 2124 and 2178.
- Identification of customers and end-users by the distributors and provision of the clients with this field notice.
- Filling Response Form and return until October 1st, 2014.
- Monitoring and reconciling the quarantine of the product as this information may be provided to the authorities.
- Reported high Calcitonin values determined with the above mentioned lots should be critically reevaluated following internal procedures regarding lookback investigations.
- Information of clinicians who received elevated Calcitonin values.
- Potential retesting of patients with elevated Calcitonin values if clinically indicated.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of this Field Safety Correction Action.

Please complete and return the enclosed response form by either fax or email as soon as possible, but not later than 1 October 2014.

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

IBL International GmbH

Contact persons in Germany:

Safety Representative / Head of Quality Department
Mr. Jörg Spangenberg
Phone: +49 (0)40/532891-0 Fax: +49 (0)40/532891-11
Joerg.Spangenberg@IBL-International.com

Signature: _____

Deputy Safety Representative / Head Quality Management and Regulatory Affairs
Name: Nicola Kaiser
Phone: +49 (0)40/532891-0 Fax: +49 (0)40/532891-11
Nicola.Kaiser@IBL-International.com

Signature: _____

RESPONSE FORM

To:	IBL International GmbH
Fax:	+49 (0)40/532891-11
Email	██████████@IBL-International.com
Re:	Urgent Field Safety Notice, 24 September 2014, Calcitonin ELISA

Customer Name:	
Contact Person:	
Contact Phone:	
Contact Email:	

Please check ALL appropriate box(es)

- I have read and understand the quarantine instructions in the 24. September 2014 letter.
- I have checked my stock and have _____ product on hold.
- I have informed my end-users of this Field Safety Notice

Any adverse events associated with product

- Yes
- No

Please check ALL boxes to describe your business

- Wholesale/Distributor
- Re-packer
- Hospital/Medical Facility
- Retailer
- Manufacturer
- Medical Laboratory

Please confirm the quantity of quarantine product remaining available for use at your facility:

Calcitonin ELISA, NM59011	Lot number	Quantity of Product Originally Shipped to Customers	Quantity of Product Available for Return
	2041		
	2124		
	2178		

PLEASE RESPOND BY 1st OCTOBER 2014!