



Urgent Field Safety Notice

Immunoassay Control – IA2640 – I364EC

Immunoassay Premium Plus Control – IA3112 – 334337 – I364EC

Complaint Reference: 242

Action Type: Device Modification

Date: 10th August 2015

Dear Valued Customer

We are currently investigating an issue with the products listed below and are providing this Urgent Field Safety Notice to inform you of this occurrence.

Detail on Affected Devices: Immunoassay Control IA2640 lot I364EC and Immunoassay Premium Plus Control IA3112 batch 334337 lot I364EC.

Description of the Problem: PTH stability has been reduced in control lot I364EC. It is now recommended that PTH is tested immediately after reconstitution.

Risk to Health: The contents of this letter should be discussed with your Medical Director. It is unlikely the error will cause misreporting of patient results as values for PTH using this lot would fall outside of the assigned ranges.

Action to be taken: Update stock with amended IFU and important notice.

Complete and return the vigilance response section of this form to technical.services@randox.com within five working days.



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Immunoassay Premium Plus Control – IA3112 – 334337 – I364EC

Transmission of Field Safety Notice: Send a copy of the FSN to all affected customers and to those who need to be aware within your organisation.

Contact Reference:

Randox Technical Services
Randox Laboratories Ltd,
55 Diamond Road,
Crumlin,
United Kingdom,
BT29 4QY
Email: technical.services@randox.com
Tel: +44 (0) 28 9445 1070
Fax: +44 (0) 28 9445 2912

Please accept our apologies for any inconvenience caused. Thank you for your patience and understanding. If you have any questions or concerns please contact Randox Technical Services.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency



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Vigilance Response Form Response Plan must be completed by the importer of the device

Importer Details

Company Name	
Address	

Total Quantity of Kits

Received from Radox	
Total quantity of kits Distributed	

Area of Distribution

To be completed by Distributors and Radox Offices

Consignee	Country	Quantity Kits Received

I have read and fully understood the Urgent Field Safety Notice and instructions provided.

Completed By		Date	
Contact	Tel		Email