



Urgent Field Safety Notice

Immunoassay Control – IA2638, IA2639, IA2640, IA2633

Immunoassay Premium Plus Control – IA3109, IA3110, IA3111, IA3112

Complaint Reference: 247

Action Type: Device Modification

Date: 7th October 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: All lots of Immunoassay Control catalogue numbers IA2638, IA2639, IA2640, IA2633 and all lots of Immunoassay Premium Plus Control catalogue numbers IA3109, IA3110, IA3111, IA3112.

Description of the Problem: Parathyroid Hormone (PTH) is present in the control material but no claim is made for the expected value or stability of this analyte.

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 would fall outside of the assigned ranges on original IFU provided.

Action to be taken: Update stock with 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 – IA3109, IA3110, IA3111, IA3112

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:

Radox Technical Services
Radox Laboratories Ltd,
55 Diamond Road,
Crumlin,
United Kingdom,
BT29 4QY
Email: technical.services@radox.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 Radox 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	