



Urgent Field Safety Notice

Magnesium – MG3880 – Rx Imola

Complaint Reference: 259

Action Type: Modification

Date: 6th April 2016

Dear Valued Customer

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

Detail on Affected Devices: MG3880

Description of the Problem: Update to Rx Imola test running order as a carryover preventative measure. Amylase or Pancreatic amylase should not be positioned directly before or after Magnesium. The tests should also not be positioned in first and last position in the running order.

Risk to Health: The contents of this letter should be discussed with your Medical Director.

Action to be taken

Review and update Rx Imola running order where required. This can be updated in the Rx Imola Parameter (F6) order screen to click and drag chemistry names to new positions.

Rework any remaining stock with updated 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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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

A handwritten signature in blue ink, appearing to read "Pave Kmsky", written over a horizontal line.



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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	Replacement Kits Required (For Device Recall Only)

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

Completed By		Date	
Contact	Tel	Email	