

RANDOX

Urgent Field Safety Notice

Lipase –LI3837, LI7979, LI8050, LI836I – RX Instruments

Complaint Reference: 267

Action Type: Modification

Date: 17th June 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: Lipase LI3837, LI7979, LI8050, LI836I

Description of the Problem: There is a possibility of reagent probe carryover from reagents Triglycerides and Direct LDL to Lipase on RX instruments, which can cause elevated Lipase results. This can occur if Lipase is positioned directly before or after Triglycerides or Direct LDL in the running order for these instruments.

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

Action to be taken: The running order for RX Instruments should be amended to prevent Lipase being positioned directly before or after Triglycerides or Direct LDL.

Alternately Lipase should be tested separately from Triglycerides and Direct LDL

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:

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

Received	
Distributed	

Area of Distribution

(To be completed by Distributors and Radox Offices)

Consignee	Country	Quantity Received	Analyser Serial Number	Replacements Required

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

Completed By		Date	
Contact	Tel		Email

