

RANDOX

Urgent Field Safety Notice

Date: 16 Feb 2018

Complaint Reference: 311 **Action Type:** Device Modification

Detail on Affected Devices:

Our records indicate that your facility may have received the following product.

Assay	Catalogue Number	GTIN
Lipase	LI3837	05055273204230
	LI8050	05055273209136
	LI8361	05055273214284
	LI7979	05055273204247

Reason for Recall:

Randox have now released further steps for contamination avoidance with the Lipase assay on RX instruments. Users should refer to the instrument testing order specifically arranging chemistries so that Lipase and Triglycerides are the last two chemistries in the test running order.

(All Other Chemistries) / (Lipase) / (Triglycerides)

In the event of an extremely elevated Lipase result cuvette maintenance steps should be performed as recommended for each RX system. The sample should then be re-tested running the Lipase assay in isolation.

Risk to Health:

The potential risk to health is limited to additional laboratory testing and/or diagnostic investigation of elevated Lipase results. The overall risk to health is negligible. Randox is not recommending a laboratory look back due to this issue.

Action to be taken:

- Update the user manual for the RX Instrument with the attached technical bulletin.
- Replace the Instructions for Use contained within the kit with the revised version.
- Discuss the contents of this notice with your Medical Director.
- Complete and return the vigilance response section of this form to technical.services@randox.com within five working days.)

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.

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Contact Reference:

Radox Technical Services

Radox Laboratories Ltd,

55 Diamond Road,

Crumlin,

United Kingdom,

BT29 4QY

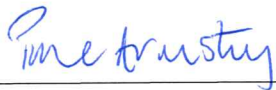
Email: technical.services@radox.com

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 Randox Offices)

Consignee	Country	Quantity Received	Analyser Serial Number	Replacements Required

I have read and understood the Urgent Field Safety Notice. The actions to be taken are completed.

Completed By				Date	
Contact	Tel		Email		

