

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

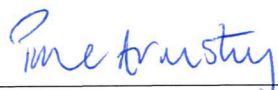
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Please accept our apologies for any inconvenience caused. Thank you for your patience and understanding. If you have any questions or concerns please contact Radox Technical Services.

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 understood the Urgent Field Safety Notice. The actions to be taken are completed.

Completed By	Date
Contact	Tel
	Email

RX Instrument Carryover Avoidance

Technical Bulletin No.:	RXTB-0083	Issue Date:	16 Feb 2018
Affected Analysers:	ALL RX Analysers		
Importance:	MEDIUM		
Items Required:	N/A		
Specialist Tools/Software:	N/A		
Software Update Required:	N/A		

Purpose:

Randox analysers and reagents are renowned for delivering the optimum test precision and accuracy. RX instruments are rigorously tested before reaching you our customer to ensure that the risk of cross-contamination is prevented. To assist with this, we recommend that the following assays are not tested in sequence on your RX instrument.

Procedure:

Methods in **Column 1** should **NOT** be directly followed by the method shown in **Column 2**:
 I.e. As shown in the table below, an **Iron test** should not follow an **Albumin test**.

Column 1	Column 2
Albumin	Iron
Glucose GODPAP	Phosphate
Uric acid	Phosphate
ALT	Phosphate
AST	Phosphate
LD	Phosphate
CK	Phosphate
ALP (AMP)	Magnesium
ALP (DEA)	Magnesium
Glucose Hexokinase	Magnesium
CKMB	Magnesium
Triglycerides	Magnesium
Cholesterol	Magnesium

Uric Acid	Magnesium
Potassium	Sodium
Direct Bilirubin	Sodium
Transferrin	Sodium
Total Protein	Sodium
Total Protein	Potassium
Total Protein	Copper
Transferrin	Chloride
Direct Bilirubin	Chloride
Cholesterol	Lipase
Triglycerides	Lipase
Potassium	LDH
Potassium	GLDH
Urea	GLDH
Creatinine*	CRP
Fructosamine	Bile acids
Amylase	Magnesium
Pancreatic amylase	Magnesium
Liquid CO2	Magnesium
Direct LDL	Lipase
Cholesterol	Calcium
TIBC	Iron
Myoglobin	HFABP
Cystatin C	HFABP
Adiponectin	HFABP
Micro-albumin	Calcium

*When testing Creatinine and CRP in the same run on the **Rx Imola**, Randox recommend using the Full Range CRP kit, Catalogue numbers CP3847 or CP3849. The use of CRP kit CP3826 is not recommended.

*Randox HFABP should be run in isolation or separated from other IT assays in the measurement order.

* Bile acids and Lipase should not be tested in the same run.

* NEFA and Triglycerides should not be tested in the same run.

*Lipase and Triglycerides should be the last two chemistries in the testing running order. (All other Chemistries) / (Lipase) / (Triglycerides).

Rx Modena Carryover Avoidance:

If Method 1 is directly followed by Method 2, the indicated wash should be applied to prevent contamination. If a wash solution is not sufficient, method 2 should **NOT** follow method 1 in the running order, alternatively this can be tested separately.

Catalogue number:

- C1 wash – RX8143
- Acid Wash – WS8397

Method 1	Method 2	Reagent Pipette	Wash solution
Albumin	Iron	R1>R1	C1 Wash
Glucose Oxidase	Inorganic phosphorus	R1>R1	C1 Wash
Uric Acid	Inorganic phosphorus	R1>R1 R2>R2	C1 Wash
Cholesterol	Calcium	R1>R1	Acid Wash
Albumin	Calcium	R1>R1	C1 Wash
TIBC	Iron	N/A	Amend running order/ test separately
CKMB	Magnesium	R1>R1	C1 Wash
Triglycerides	Magnesium	R1>R1	C1 Wash
CK	Magnesium	R1>R1	Acid Wash
ALP AMP	Magnesium	R1>R1	Acid Wash
ALP DEA	Magnesium	R1>R1	Acid Wash
Glucose Hexokinase	Magnesium	R1>R1	Acid Wash
Amylase	Magnesium	R1>R1	Acid Wash
LCO ₂	Magnesium	R1>R1	Acid Wash
Micro-albumin	Calcium	R1>R1	Acid Wash

If you require any further information about this, please contact your local Randox Representative or Technical Support.

**Randox Customer Services Action Centre: +44 (0) 28 9445
1070**

technical.services@randox.com