

RANDOX

Urgent Field Safety Notice

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Date Issued: 30 November 2018

Complaint Reference: REC359

Action Type: Device Modification

Detail on Affected Devices:

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

Device Name	Catalogue Number	GTIN
Calcium	CA3871	05055273200904
	CA8309	05055273208368
	CA8021	05055273208351

Reason for Recall:

Randox have released an update to the carryover avoidance technical bulletin to introduce additional steps for reagent carryover avoidance with the Calcium assay on RX instruments. The instrument testing order should be reviewed in line with the updated technical bulletin. Additional pipette washes can also be implemented as described in the technical bulletin.

Risk to Health:

Carryover to the Calcium reagent would be observed as inconsistencies in Quality control recovery which may lead to a delay in running patient samples or erroneous elevated test results.

Action to be taken:

- Review your instrument testing order in line with the carryover avoidance technical bulletin. Enable additional pipette washes.
- Update the RX user manual with the updated carryover avoidance document and ensure all operators are aware of the recommendations.
- Discuss the contents of this notice with your Medical Director.
- Complete and return the response form to technical.services@randox.com within five working days.

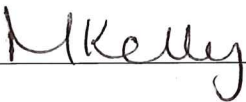
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Transmission of Field Safety Notice: Send a copy of the FSN to all affected customers and to those who need to be aware within your organisation.

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



RX Instrument Carryover Avoidance

Technical Bulletin No.:	RXTB-0098	Issue Date:	20 th Nov 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
Urea	Calcium
Creatinine (Jaffe)	Calcium
Total Protein	Calcium
LDH	Calcium
Total Bilirubin	Calcium
Phosphorus	Calcium
ALP	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
Urea	Calcium	R1>R1	Acid Wash
Creatinine (Jaffe)	Calcium	R1>R1	Acid Wash
Total Protein	Calcium	R1>R1	Acid Wash
LDH	Calcium	R1>R1	Acid Wash
Total Bilirubin	Calcium	R1>R1	Acid Wash

Rx Imola 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:

- Acid Wash – WS3853

Method 1	Method 2	Reagent Pipette	Wash solution
Urea	Calcium	R1>R1	Acid Wash
Creatinine (Jaffe)	Calcium	R1>R1	Acid Wash
Total Protein	Calcium	R1>R1	Acid Wash
LDH	Calcium	R1>R1	Acid Wash
Total Bilirubin	Calcium	R1>R1	Acid Wash

Rx Daytona Plus 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:

- Acid Wash – WS8397

Method 1	Method 2	Reagent Pipette	Wash solution
Urea	Calcium	R1>R1	Acid Wash
Creatinine (Jaffe)	Calcium	R1>R1	Acid Wash
Total Protein	Calcium	R1>R1, R2>R2	Acid Wash
LDH	Calcium	R1>R1	Acid Wash
Total Bilirubin	Calcium	R1>R1	Acid Wash
Phosphorus	Calcium	R1>R1	Acid Wash
ALP	Calcium	R1>R1	Acid Wash

Rx Daytona 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:

- Acid Wash – WS3853

Method 1	Method 2	Reagent Pipette	Wash solution
Urea	Calcium	R1>R1	Acid Wash
Creatinine (Jaffe)	Calcium	R1>R1	Acid Wash
Total Protein	Calcium	R1>R1, R2>R2	Acid Wash
LDH	Calcium	R1>R1	Acid Wash
Total Bilirubin	Calcium	R1>R1	Acid Wash
Phosphorus	Calcium	R1>R1	Acid Wash
ALP	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

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