Urgent Field Safety Notice

Date: 1st August 2017

Complaint Reference: 305 **Action Type:** Device Recall

Detail on Affected Devices:

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

Assay	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
Liquid Cardiac Control Level 3	CQ5053 CQ035/001/ CQ035	05055273207460	4069CK	2018-08	2016-08

Reason for Recall:

Randox Laboratories has confirmed Troponin T and Troponin I levels in lot 4069CK have deteriorated. This may result in recovery outside the assigned range.

Risk to Health:

As Troponin T and Troponin I results may fall outside of the assigned range, quality control failure is possible. In this instance a delay in patient result reporting could occur. However, this may be mitigated with use of control level 1 and 2 which are not affected by this recall.

A review of patient results is not required as control under recovery is evident at the time of use.

Action to be taken:

- Discontinue use of and discard any of the above immediately.
- Review your reagent inventory of these products and assess your laboratories needs for reimbursement for discarded inventory and provide proof of scrappage for discarded material.
- Discuss the contents of this notice with your Medical Director.
- Compliance with your country's Regulatory Authority requires a return of the attached response form. Complete and return the vigilance response section of this form to technical.services@randox.com within five working days.)

Form No. 6307-TS
REVISION (8)
27th September 2016

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

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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		

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