

# RANDOX

## Urgent Field Safety Notice

**Date:** 1<sup>st</sup> 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](mailto:technical.services@randox.com) within five working days.)

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## Urgent Field Safety Notice

**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](mailto: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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## Urgent Field Safety Notice

**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		