RANDOX
Urgent Field Safety Notice

Date: 25th April 2017

Complaint Reference: 287 **Action Type:** Device Modification

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
CKMB	CQ5053	5055273207460	3912CK	28th October 2017	7th November 2016

Reason for Recall:

Randox has confirmed a change in recovery with regards to CKMB in lot 3912CK of the Liquid Cardiac Control. A similar issue with Myoglobin has previously been reported for this lot. All other analytes recover as expected.

The IFU has been updated to indicate in the limitations section that values for CKMB and Myoglobin may gradually decrease over the product shelf-life for the Liquid Cardiac Controls (CQ5051, CQ5052 and CQ5053).

Risk to Health:

The quality control results which are not within range can lead to a delay in reporting CKMB results however as CKMB is no longer used as the primary test for diagnosing cardiac injury this therefore should not pose a serious risk to health.

Action to be taken:

- Place a copy of the important notice in all kits.
- 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. Please 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

RANDOX

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:

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

Irene Armstrong

27 April 2017

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

RANDOX

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 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		

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