RANDOX

Urgent Field Safety Notice

Liquid Cardiac Control - CQ5051 – 4144CK

Date: 16th February 2018

Complaint Reference: 318 **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
Liquid Cardiac Control Level 1	CQ5051	05055273207446	4144CK	28-03-2019	31-Oct-2017

Reason for Recall:

The Troponin I value on the insert for 4144CK is quoted to the wrong decimal place for the Abbott Architect STAT hs analyser. Values are quoted as 0.990ng/ml and 990ng/l and should be 0.099ng/ml and 99.0ng/l respectively.

Risk to Health:

This will result in this control reporting out of range and subsequently a delay in reporting patient results. A delay in reporting patient results could lead to a delay in patient diagnosis.

Action to be taken:

- Replace kit IFU with correct revision (please see attached)
- 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.)

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

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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.

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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