RANDOX
Urgent Field Safety Notice

Date: 6th February 2017

Complaint Reference: 285 **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
CRP calibrator	CP2479	05055273201697	398677	28th Feb 2018	21st Oct 2016

Reason for Recall:

Randox identified a labelling error on the value sheet of CRP calibrator CP2479. The target concentrations quoted on the IFU for calibrator levels 5 and 6 were 1.08mg/dl and 2.15mg/dl. The correct values are 10.75mg/dl and 21.49mg/dl respectively.

Risk to Health:

The analyser will fail to calibrate leading to delay in diagnosis as the assay will not run.

Action to be taken:

- Value sheet has been updated and should be placed into any remaining stock. (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.)

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

Pine Kinsley

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

RANDOX

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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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