



Urgent Field Safety Notice

Liquid Chemistry Premium plus Control

LUE5095 – 76 IUE

Complaint Reference: 22

Action Type: Product Recall

Date: 22-Sep-15

Dear Valued Customer

We are currently investigating an issue with the product listed below and are providing this Urgent Field Safety Notice to inform you of this occurrence.

Detail on Affected Devices: Liquid Chemistry Premium plus Control LUE5095 lot 76 IUE

Description of the Problem: Liquid Chemistry Premium plus Control LUE5095 Lot 76 IUE is subject to a Recall due to Bilirubin Instability.

Risk to Health: The contents of this letter should be discussed with your Medical Director.

Action to be taken: Quarantine the affected products and provide photograph evidence of scrappage.

Complete the vigilance response section of this form detailing the quantity of replacement kits required. Return the vigilance response form to technical.services@randox.com within 5 working days for replacement material to be arranged.



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Transmission of Field Safety Notice: Send a copy of the Notification to all affected customers and to those who need to be aware within your facility.

Contact Reference:

Radox Technical Services
Radox Laboratories Ltd,
55 Diamond Road,
Crumlin,
United Kingdom,
BT29 4QY
Email: 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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Vigilance Response Form (Response Plan must be completed by the importer of the device)

Importer Details

Company Name	
Address	

Total Quantity of Kits

Received from Radox	
Total quantity of kits Distributed	

Area of Distribution

(To be completed by Distributors and Radox Offices)

Consignee	Country	Quantity Kits Received	Replacement Kits Required (For Device Recall Only)

I have read and fully understood the Urgent Field Safety Notice and instructions provided.

Completed By		Date	
Contact	Tel	Email	