



## Urgent Field Safety Notice

Liquid Urine Control Level 2 UC5074 Lot 764UC

**Complaint Reference:** 220

**Action Type:** Device Modification

**Date:** 21<sup>st</sup> January 2015

Dear Valued Customer

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

**Detail on Affected Devices:** Catalogue Number: UC5074 Lot: 764UC (Glucose Hexokinase value Roche Cobas C Series instruments only)

**Description of the Problem:** It has been discovered that the value for Glucose Hexokinase for the Roche Cobas C series instrument has been assigned incorrectly. The value was assigned at 38.9 mg/dl / 2.16 mmol/l and should have been 25.7 mg/dl / 1.43 mmol/l.

**Risk to Health:** The contents of this letter should be discussed with your Medical Director. The assignment error will most likely not cause a misreporting of patient results as control values for Glucose using lot 764UC on the Roche Cobas C Series would be noticeably outside the assignment range.

**Action to be taken:** Importers of the device Update existing stock with attached amended values sheet. End users FSN applies only to Roche Cobas C series instruments value for Glucose Hexokinase.

Complete and return the vigilance response section of this form to [technical.services@randox.com](mailto:technical.services@randox.com) within five working days.



## Urgent Field Safety Notice

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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](mailto: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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### Liquid Urine Control Level 2 UC5074 Lot 764UC

**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	



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