

RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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Tel: +44 (0) 28 9445 1070

Date Issued: 22 Feb 2019

Complaint Reference: REC376

Action Type: Device Recall

Detail on Affected Devices: Urinalysis Control – Level 2 (URNAL CONTROL 2)

Our records indicate that your facility may have received the following product

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
Urinalysis Control – Level 2	UC5034	05055273207590	982UC	28 Dec 2019	19 June 2018

Reason for Recall:

Randox has confirmed that the analyte Nitrite is failing to report as "Positive" for some vials of UC5034 - Urinalysis Control Level 2 - lot: 982UC. The control material does not meet the specific performance characteristics as quoted in the kit insert.

Risk to Health:

The nitrite test is commonly used in diagnosing urinary tract infections (UTIs). Inability to use the dipstick method could result in a delay in diagnosis. This could result in prolonged discomfort for the patient.

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Action to be taken:

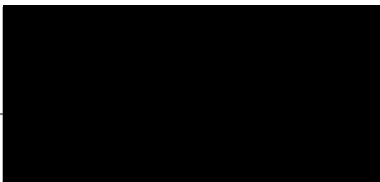
- Discontinue use of and discard any remaining stock of UC5034 lot 982UC immediately.
- Review your Quality Control inventory of this product and assess your laboratories needs for replacement material.
- Discuss the contents of this notice with your Medical Director. A review of previous patient results is not required as an incorrect control result is apparent at the time of use.
- Please retain this letter with your laboratory records and forward to those who may have received this product.
- Complete and return the response 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.

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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Please check ALL appropriate boxes.

- I have read and understand the recall instructions provided in the Field Safety Notice.
- I have checked my stock and have quarantined the affected kits.
- I have notified all those who need to be aware of this notice within the organisation.

Indicate disposition of recalled product:

- quarantined pending destruction (*specify quantity*);
- destroyed (*specify quantity, date and method*);

Customer Details

Company Name	
Address	

Total Quantity

Received	
Distributed	

Area of Distribution (To be completed by Distributors and Radox Offices)

- I have identified and notified my customers that were shipped or may have been shipped this product by (*specify date and method of notification*); **OR**
- Detailed below is a list of customers who received/may have received this product. Please notify my customers. (List of customers may also be sent in a separate attachment)

Have you been notified of any adverse events associated with recalled product?

- YES
- NO

If yes, please explain: _____

Consignee	Country	Quantity Received	Device Serial / Lot Number	Replacements Required

Completed By	Print Name:	Date	
	Signature:		
Contact Telephone			
Contact Email			

Complete and return the response form to technical.services@radox.com within five working days.