

RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
55 Diamond Road Crumlin
United Kingdom BT29 4QY
technical.services@randox.com
Tel: +44 (0) 28 9445 1070

Date Issued: 17 Jul 2019

Complaint Reference: REC 413

Action Type: Device Modification

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	1020UC	28 May 2020	16 Nov 2018

Reason for Recall:

The analyte range for Leukocytes for use with the Siemens Multistix method has been re-assigned to NEGATIVE to 3+.

Risk to Health:

QC recovery outside range will require retesting of the control. There is negligible risk to health.

Action to be taken:

- Discard current revision of the Value Sheet and replace with the revised copy available at www.randox.com
- Discuss the contents of this notice with your Medical Director. Review results generated with the affected batches in line with the clinical profile of the patient.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.
- Complete and return the response form 12187-QA to technical.services@randox.com within five working days.

Transmission of Field Safety Notice:

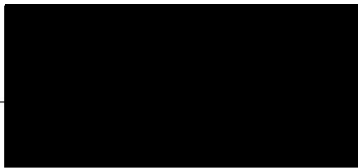
Send a copy of the FSN to all affected customers and to those who need to be aware within your organisation.

RANDOX
Urgent Field Safety Notice

Radox Laboratories Ltd
55 Diamond Road Crumlin
United Kingdom BT29 4QY
technical.services@radox.com
Tel: +44 (0) 28 9445 1070

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.



Please complete this form even if you do not have any affected stock.

Date Issued: 17 July 2019

Complaint Reference: REC413

Action Type: Device Modification

Detail on Affected Devices:

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	1020UC	28 May 2020	16 Nov 2018

Please check ALL appropriate boxes.

- I have read and understand the instructions provided in the Field Safety Notice.
- I have checked my stock and identified the affected kits.
- I have notified all those who need to be aware of this notice within the organisation.
- Field Safety Notice is not applicable to my use of the product.

Indicate disposition of recalled product:

- no affected stock
- replaced the Value Sheet of the affected lot (*specify quantity*);

Customer Details

Company Name	
Address	

Total Quantity

Received	
Distributed	

RANDOX

Response Form

Radox Laboratories Ltd
55 Diamond Road, Crumlin
United Kingdom BT29 4QY
technical.services@radox.com
Tel: +44 (0) 28 9445 1070

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

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

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your regulatory authority requires your response form as evidence of the effectiveness of the corrective actions detailed in the FSN.

PART 2 (To be completed by Distributors and Radox Offices only)

Area of Distribution

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)

Consignee	Country	Quantity Received	Analyser / Kit Serial / Lot Number	Replacements Required

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

YES

NO

If yes, please explain: _____