RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
55 Diamond Road Crumlin
United Kingdom BT29 4QY
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Tel: +44 (0) 28 9445 1070

Date Issued: 28 Jun 23

Complaint Reference: REC679

Action Type: Device Recall

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
Liquid Urine Control Level 2	UC5074	05055273207569	1209UC	28 Mar 24	28 Apr 22

Reason for Action:

Randox Laboratories is conducting a Device Recall for Liquid Urine Controls Level 2, UC5074, lot 1209UC due to the following:

- There is vial to vial variation resulting in some vials recovering positive for hCG, which should be negative and high and outside range for cortisol.
- There has been a transcription error for Creatinine in the Instructions For Use (IFU) The target and ranges for Creatinine for the Roche Creatinine Plus method have been listed incorrectly.

Risk to Health:

An incorrect control result from one of the affected vials may cause a delay in reporting patient results. hCG test are run on urine to confirm pregnancy and can also be measured as a tumour marker test.

Action to be taken:

- Discontinue use of and discard any of the above immediately. **Provide Randox with photographic evidence of the destruction of the kits.**
- Review your inventory of these products and assess your laboratories needs for reimbursement for discarded inventory.
- Review previous results for this controls and ensure patient results were not reported if control results were not within range.

Form No. 6307-TS
REVISION (10)
4th Feb 2019

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- 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.

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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Response Form

Randox Laboratories Ltd
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Please complete this form *even if you do not have any affected stock*.

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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 affected product

- ❑ no affected stock
- ❑ destroyed (*specify quantity, date and method*); **Provide Randox with photographic evidence of the destruction of the kits.**

Customer Details

Company Name	
Address	

Total Quantity

Received	
Distributed	

Form No. 12187-QA
REVISION (3)

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Response Form

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

Complete and return the response form to technical.services@randox.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.

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PART 2 (To be completed by Distributors and Randox 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*);

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: _____