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: 1st Feb 23

Complaint Reference: REC637

Action Type: Product 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
CRP	CP7950	05055273201826	588447	28 Jan 24	28 Jul 22
	CP3826	05055273201765	588079	28 Jul 23	5 Jan 22
			588434	28 Jan 24	28 Jul 22
			599779	28 Mar 24	11 Apr 22
			614987	28 Jul 24	5 Sep 22

Reason for Action:

Randox is conducting a Device Recall for CRP Immunoturbidimetric reagent catalogue numbers CP7050, batch 588447 and CP3826, batches 588434, 588079, 599779 and 614987. The Antibody (R2 reagent) in these batches is showing a positive bias compared to previous batches on patient samples. (See Figure 2 below). Quality Controls do not show the same bias and will be within range (See Figure 1 below)

Figure 1: Quality Control Results Comparison

	Target	Range	Previous Reagent Batch	Recalled Reagent Batch	% Dev
Randox QC Level 1	23.9	19.1-28.7	21.80	21.75	-0.22
Randox QC Level 2	46.0	36.8- 55.2	44.46	48.63	9.37
Randox QC Level 3	68.8	55.1-82.7	69.93	70.77	1.20

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

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Figure 2: Patient Serum Samples Comparison

	Previous Reagent Batch (mg/l)	Recalled Reagent Batch (mg/l)
Patient 1	9.98	18.03
Patient 2	7.35	13.07
Patient 3	6.83	14.92
Patient 4	4.75	18.03
Patient 5	5.59	14.92
Patient 6	6.54	7.19
Patient 7	6.97	11.70

Risk to Health:

Potential to misclassify patient samples above the reference range of 5mg/l. CRP is an acute phase reactant and is released by the liver into the blood following a tissue injury, infection or inflammation. The test is not diagnostic for any particular condition but can indicate the level of inflammation present and can be used to monitor treatment.

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 reagent inventory of these products and assess your laboratories needs for reimbursement for discarded inventory.
- Review results generated with the affected batches in line with the clinical profile of the patient.
- Discuss the contents of this notice with your Medical Director.
- 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.

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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 affected stock.**

Form No. 12187-QA
REVISION (2)
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RANDOX

Response Form

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

Customer Details

Company Name	
Address	

Total Quantity

Received	
Distributed	

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.

Form No. 12187-QA
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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*);

  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: _____

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