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: 20th September 2023

Complaint Reference: REC692

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
Glucose-6-Phosphate Dehydrogenase (G-6-PDH)	PD410	05055273204797	629055	28th Feb 2026	25th April 2023

Reason for Action:

Randox Laboratories is conducting a Device Recall for G-6-PDH reagent, catalogue number PD410, batch 629055. The R2 NADP and R3 Substrate are showing low rate of absorption change, resulting in cases of low or no reaction taking place, leading to low QC recovery to target and patient results reported below the normal range in erythrocytes 245-299 mU/10^9 & 6.97 -20.5 U/g Hb (+37°C).

Risk to Health:

G6PD is a protective enzyme found within red blood cells, PD410 batch 629055 has the potential to misclassify patient samples below the normal range erythrocytes 245-299mU/10^9 & 6.97 -20.5 U/g Hb (+37°C).

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.

Form No. 6307-TS
REVISION (10)

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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.

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

Form No. 6307-TS
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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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Glucose-6-Phosphate Dehydrogenase (G-6-PDH)	PD410	05055273204797	629055	28th Feb 2026	25th April 2023

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	

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Response Form

Randox Laboratories Ltd
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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.

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Response Form

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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: _____