

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	28 th Feb 2026	25 th 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/10⁹ & 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/10⁹ & 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.

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 Radox Technical Services.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

A handwritten signature in black ink, appearing to be 'Louise', written over a horizontal line.