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: 01 May 2019
Complaint Reference: REC383 (rev 1) **Action Type:** Device modification

Detail on Affected Devices: G-6-PDH Deficient Control (G-6-PDH CONTROL D)
G-6-PDH Normal Control (G-6-PDH CONTROL N)

Our records indicate that your facility may have received the following product

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
G-6-PDH Deficient Control	PD2617	05055273204773	687PD 700PD 715PD	28 Aug 2019 28 Jan 2020 28 July 2020	16 Jan 2018 28 May 2018 20 Dec 2018
G-6-PDH Normal Control	PD2618	05055273204780	676PD 701PD 716PD	28 July 2019 28 Jan 2020 28 July 2020	26 Oct 2017 8 May 2018 21 Dec 2018
G-6-PDH	PD410	05055273204797	all	n/a	n/a

Reason for Action:

Randox is conducting a Field Safety Corrective Action for G6PDH Deficient and Normal Controls for the lots specified in the table above. The target values and ranges in these lots are incorrect. Please refer to the attached value sheets with the reassigned target values for the affected lots.

Customers are reminded to follow the assay protocol for G6PDH in the Instructions for Use (catalogue number PD410) which instruct the user to calibrate using the factor provided. Please refer to the table below regarding the updated calibration factors for G6PDH on RX analysers. For customers with third party analysers, please refer to the factor quoted on the instrument specific application sheet which has not changed.

Analyser	Calibration Factor
RX DAYTONA	19310
RX DAYTONA+	21048
RX IMOLA	21048
RX MONACO	21048

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

Risk to Health:

Many individuals that are glucose-6-phosphate dehydrogenase deficient are asymptomatic most of the time, however when they are exposed to certain triggering factors, they can develop acute haemolytic anaemia (AHA), which can be life-threatening, especially in children. In most cases removal of the trigger will resolve the symptoms. However, in very rare severe cases a delay in treatment can lead to kidney failure or death.

Action to be taken:

- Review your inventory and replace the Value Sheet in all control kits (catalogue numbers PD2617 and PD2618)
- Review the parameters on your analyser and confirm the correct factor is detailed.
- 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.
- Inform all relevant staff members. If you have supplied or transferred any potentially affected product to another facility or organisation, let that facility know of the recall immediately by providing a copy of this FSN and response form.
- 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

Last printed: 01 May 2019

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

RANDOX

Response Form

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

Date Issued: 01 May 2019
Complaint Reference: REC383 (rev 1) **Action Type:** Device modification

Detail on Affected Devices: G-6-PDH Deficient Control (G-6-PDH CONTROL D)
G-6-PDH Normal Control (G-6-PDH CONTROL N)

Our records indicate that your facility may have received the following product

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
G-6-PDH Deficient Control	PD2617	05055273204773	687PD 700PD 715PD	28 Aug 2019 28 Jan 2020 28 July 2020	16 Jan 2018 28 May 2018 20 Dec 2018
G-6-PDH Normal Control	PD2618	05055273204780	676PD 701PD 716PD	28 July 2019 28 Jan 2020 28 July 2020	26 Oct 2017 8 May 2018 21 Dec 2018

Please check ALL appropriate boxes.

- ❑ I have read and understand the recall instructions provided in the Field Safety Notice.
- ❑ I have checked my stock and have quarantined the affected kits.
- ❑ I have notified all those who need to be aware of this notice within the organisation.

Indicate disposition of recalled product:

- ❑ Replaced the Value Sheet in PD2617 and PD2618 (*specify quantity*);
- ❑ Confirmed the correct calibration factor on the instrument settings

Customer Details

Company Name	
Address	

Total Quantity

Received	
Distributed	

RANDOX

Response Form

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

Area of Distribution (To be completed by Distributors and Randox Offices)

- ❑ 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)

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

- ❑ YES
- ❑ NO

If yes, please explain: _____

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

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.