RANDOX

# Urgent Field Safety Notice

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Date Issued: 4 Nov 2020

Complaint Reference: REC 490 Action Type: 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 |
|---|---|---|---|---|---|
| Magnesium | MG3880 | 05055273204629 | 539734 | 28 March 2022 | 30 Sept 2020 |
| Magnesium | MG8326 | 05055273209303 | 539770 | 28 March 2022 | 30 Sept 2020 |

Reason for Action:

Randox can confirm the magnesium batches above are failing to meet the linearity performance claims quoted on the kit inserts:

| Catalogue Number | Sample Type | mmol/l | mg/dl |
|---|---|---|---|
| MG3880 | Serum / Plasma | 3.27 | 8.01 |
| MG3880 | Urine | 21.4 | 52.0 |
| MG8326 | Serum / Plasma | 3.50 | 8.57 |
| MG8326 | Urine | 21.3 | 51.7 |

The linearity is reduced by approximately -30% for Serum / Plasma and -50% for Urine in MG3880, batch 539734 and MG8326, batch 539770. Patient results within the normal range are not affected.

Risk to Health:

No risk to health, magnesium can be tested alongside Calcium, Potassium and Phosphorous during investigation into kidney function for example.

Action to be taken:

- Discontinue use of and discard any of the above immediately.
- Review your reagent inventory of these products and assess your laboratories needs for reimbursement for discarded inventory.



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

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- 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 Randox Technical Services.

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

Declan Kane