RANDOX

Urgent Field Safety Notice

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

Date Issued: 22 June 2020

Complaint Reference: REC471

Action Type: Device 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
Lipase Colorimetric Reagent	LI3837	05055273204230	507360	28-Oct-20	23-Oct-19
Lipase Colorimetric Reagent	LI3837	05055273204230	497086	28-Oct-20	19-Jul-19
Lipase Colorimetric Reagent	LI7979	05055273204247	497053	28-Oct-20	19-Jul-19
Lipase Colorimetric Reagent	LI8050	05055273209136	497038	28-Oct-20	19-Jul-19
Lipase Colorimetric Reagent	LI8361	05055273214284	502135	28-Oct-20	13-Sep-19
Lipase Colorimetric R1 Buffer	LI011/004/UL	N/A	1048LI	28-Oct-20	25-Jun-19
Lipase Colorimetric R2 Substrate	LI015/000/UL	N/A	1049LI	28-Oct-20	24-Jun-19
Lipase Colorimetric R2 Substrate	LI015/003/UL	N/A	1049LI	28-Oct-20	9-Jul-19
Lipase Colorimetric R1 Buffer	LI011/000/UL	N/A	1050LI	28-Oct-20	25-Jun-19
Lipase Colorimetric R2 Substrate	LI015/000/UL	N/A	1051LI	28-Oct-20	21-Jun-19

Reason for Action:

Randox have confirmed imprecision of quality control and patient samples when using Randox Lipase reagent batches listed in the table above. **Please find a list of actions to be taken on page 2.**

Randox is actively working to investigate the root cause.

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Risk to Health:

The potential exists for misinterpretation of lipase values which may lead to a delay in diagnosis. The potential exists for the incorrect diagnosis of pancreatitis. Diagnosis should be made in conjunction with clinical symptoms. Pancreatitis can cause Amylase and Lipase levels to be increased up to 3 times normal. Both values should be increased, in order to carry the diagnosis of pancreatitis.

Action to be taken:

- Discontinue use of and scrap any of the above batch numbers immediately.
- Keep proof of scrappage (this should be provided along with the response form 12187-QA).
- Review your reagent inventory of these products and assess your laboratories replacement needs for reimbursement of discarded inventory.
- Review results generated with the affected batches in line with the clinical profile of the patient.
- Please review this letter 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

Last printed: 19 June 2020

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REVISION (10)
4th Feb 2019