RAND®X

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: 30 Aug 2019
Comp laint Reference: REC 407

Action Type: Device Modification

Detail on Affected Devices: Rheumatoid Factor

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

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
Rheumatoid Factor Standard (RF CAL)	RF2 301	05055273205039	463479/ 1325 -1329RF	28 Oct 2019	Aug 2018
			466715/ 1325 -1329RF	28 Oct 2019	Aug 2018
			474059/ 1339 -1343RF	28 Apr 2020	Dec 2018
			480410/ 1347-1351RF	28 Apr 2020	Dec 2018
Liquid Pro tein Calibrators (SP CAL (LIQ))	IT2691	5055273204032	440973 / 1748 - 1752 1T	28 Sept 2019	Jan 2018
			451414 / 1748-17521T	28 Sept 2019	Apr2018
			470531/ 1813 - 18171T	28 June 2020	Jan 2019
			480859 / 1813 - 18171T	28 Jun e 2020	Feb 2019

Reason for Action:

Randox is conducting a Device Modification for Rheumatoid Factor Standard and Liquid Protein Calibrator for the lots specified in the table above. The assigned value for Rheumatoid Factor over recovers against the reference material RF serum, 1st British standard from NIBSC. Ref = 64/002.
The calibrator values have been adjusted to re-align to the reference material.

Please refer to the new calibrator concentration target s found in the attached revised value sheet. Customers may observe a decrease of approximately 21% in their patient results and controls.

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

Last print ed: 02 Septe mber 2019

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Risk to Health:

Reporting of a false abnormal result may lead to unnecessary additional testing.

Action to be taken:

- Review your reagent inventory and replace the value sheet with the new values provided.
- 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

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