RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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Date Issued: 19 Jul 23

Complaint Reference: REC684

Action Type: Device Modification

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
Liquid Protein Calibrators	IT2691	05055273204032	590858	28 Aug 23	16 Dec 21
			590859	28 Aug 23	29 Aug 21
			627222	28 Jul 24	29 Jul 22
			627224	28 Jul 24	20 Jan 23
			634886	28 Jul 24	29 Jul 22
			634887	28 Jul 24	27 Mar 23

Reason for Action:

As part of our ongoing quality monitoring, Randox Laboratories have restandardised Ferritin in Liquid Protein Calibrators, IT2691, to reference material NISBC 19/118. Current calibrators lots 2112IT-2116IT, packed into batches 627222, 627224, 634886 and 634887 have been reassigned as part of the restandardisation.

Ferritin results for Quality Control material and patient samples is expected to recover higher by approximately +10% across the assay range following this restandardisation. Updated calibrator targets for the batches have been listed in Table1 below. The updated Instructions For Use (IFU) is available on www.randox.com, please discard the previous version of the IFU and download the latest version.

Table 1

Lot Number	Previous Target (ng/ml)	Updated Target (ng/ml)
2112IT	23.4	23.9
2113IT	47.2	54.2
2114IT	96.9	102.6
2115IT	190.5	216.4
2116IT	423.5	483.6

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

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Any customers using batches 590858 and 590859 for Ferritin, please contact technical.services@randox.com

Risk to Health:

Ferritin is an iron storage protein, and a test may be ordered along with other iron status test in a patient suffering from symptoms suggestive of iron deficiency anaemia.

Potential to misclassify patient results due to an incorrectly reported result, however, Ferritin results are likely to be reviewed along with other iron status tests.

Action to be taken:

- 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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