

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: 3 Aug 23

Complaint Reference: REC685

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 Assayed Chemistry Control Premium Plus Level 3	LAE4215	05055273208986	1308UE	28 Feb 25	22 Mar 23

Reason for Action:

Randox Laboratories can confirm that there has been a transcription error in the Instructions for Use (IFU) for the Liquid Assayed Chemistry Control Premium Plus Level 3, LAE4215, lot 1308UE. For Caeruloplasmin, the one and two standard deviation values printed on the sheet are incorrect. The target and range values are correct. The IFU has been updated and is available on www.randox.com. Please discard the incorrect IFU and download the updated IFU. Please refer to the table below for the correction.

Analyte	Incorrect Values		Correct Values	
	1SD	2SD	1SD	2SD
Caeruloplasmin	0.13 g/l	0.26 g/l	0.04 g/L	0.07 g/L
	13.05 mg/dl	26.10 mg/dl	3.64 mg/dL	7.28 mg/dL

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Risk to Health:

Caeruloplasmin is a copper-binding protein, and a test may be ordered alongside copper tests for the diagnosis of Wilsons disease.

There is a potential to misreport patient results following a Quality Control result with a large standard deviation. However, other Quality Control samples are likely to be run in conjunction with the affected batch and patient Caeruloplasmin results are likely to be reviewed alongside other tests, symptomology and patient history.

Action to be taken:

- Review Quality Control data generated using the affected lot.
- Discuss the contents of this notice with your Medical Director.
- Complete and return the response form 12187-QA to technical.services@radox.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 Radox Technical Services.

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

