

# RANDOX

## Urgent Field Safety Notice

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Tel: +44 (0) 28 9445 1070

**Date Issued:** 29 Nov 23

**Complaint Reference:** REC704

**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
Copper	CU2340	050552732019	592278	28 Feb 24	25 Mar 22
			610661	28 Aug 24	7 Oct 22
			610669	28 Aug 24	29 Aug 22
			629021	28 Feb 25	24 Mar 23
			647201	28 Sep 25	3 Oct 23
			657944	28 Aug 24	29 Aug 22

### Reason for Action:

Randox Laboratories have released an update to the Carryover Avoidance Technical Bulletin to detail that Copper, should not be run directly after Total Protein, on the RX series instruments testing order. **If reagent carryover persists, avoid running Copper on analysers that run Total Protein.**

Please discard all previous version of the Carryover Avoidance Technical Bulletin and replace with the updated version.

### Risk to Health:

Interference to the Copper assay can lead to an increase in Quality Control and patient results, which may lead to a delay in running patient samples or increased test results.

### Action to be taken:

- Review your instrument testing order in line with the Carryover Avoidance Technical Bulletin (RXTB-0148)

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- Update the RX user manual with the updated Carryover Avoidance Technical Bulletin (RXTB-0148) and ensure all operators are aware of the recommendations.
- Discuss the contents of this notice with your Medical Director.
- Complete and return the response form 12187-QA to [technical.services@radox.com](mailto: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**

A handwritten signature in black ink, appearing to read 'Kang Lu', is written over a horizontal line. The signature is stylized and includes a long horizontal stroke extending to the right.