RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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United Kingdom BT29 4QY
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Tel: +44 (0) 28 9445 1070

Date Issued: 17 Jul 2019
Complaint Reference: REC 413 **Action Type**: Device Modification

Detail on Affected Devices: Urinalysis Control – Level 2 (URNAL CONTROL 2)

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

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
Urinalysis Control – Level 2	UC5034	05055273207590	1020UC	28 May 2020	16 Nov 2018

Reason for Recall:

The analyte range for Leukocytes for use with the Siemens Multistix method has been re-assigned to NEGATIVE to 3+.

Risk to Health:

QC recovery outside range will require retesting of the control. There is negligible risk to health.

Action to be taken:

- Discard current revision of the Value Sheet and replace with the revised copy available at www.randox.com
- Discuss the contents of this notice with your Medical Director. Review results generated with the affected batches in line with the clinical profile of the patient.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.
- 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.

Form No. 6307-TS
REVISION (9)
24th October 2018

Last printed: 17 July 2019

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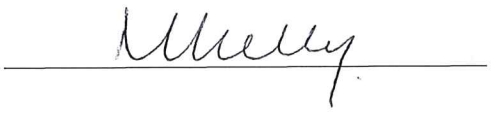
Please accept our apologies for any inconvenience caused. Thank you for your patience and understanding. If you have any questions or concerns please contact Randox Technical Services.

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



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