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: 22 Feb 2019
Complaint Reference: REC376 **Action Type**: Device Recall

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	982UC	28 Dec 2019	19 June 2018

Reason for Recall:

Randox has confirmed that that the analyte Nitrite is failing to report as "Positive" for some vials of UC5034 - Urinalysis Control Level 2 - lot: 982UC. The control material does not meet the specific performance characteristics as quoted in the kit insert.

Risk to Health:

The nitrite test is commonly used in diagnosing urinary tract infections (UTIs). Inability to use the dipstick method could result in a delay in diagnosis. This could result in prolonged discomfort for the patient.

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Action to be taken:

- Discontinue use of and discard any remaining stock of UC5034 lot 982UC immediately.
- Review your Quality Control inventory of this product and assess your laboratories needs for replacement material.
- Discuss the contents of this notice with your Medical Director. A review of previous patient results is not required as an incorrect control result is apparent at the time of use.
- Please retain this letter with your laboratory records and forward to those who may have received this product.
- Complete and return the response form 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.

Pine Armstrong

Form No. 6307-TS
REVISION (9)
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