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: 10th June 2022

Complaint Reference: REC601

Action Type: Device Modification

Detail on Affected Devices:

Our records indicate that your facility may have received the following products:

Device Name	Catalogue Number	GTIN	Batch / Lot number
DRUGS OF ABUSE ARRAY URINE (CE) MultiSTAT	EV4346	05055273216219	605466, 594893, 591866
DRUGS OF ABUSE ARRAY BLOOD (CE) MultiSTAT	EV4347	05055273216288	596699, 594818, 591482

Reason for Action:

An occurrence of rotated biochips in the cartridge of Drugs of Abuse Urine (CE) MultiSTAT kit (batch 594893) has been identified. As a result of this analytes have been incorrectly reported as positive. The follow-up confirmatory analysis correctly identified the sample as negative. The panel parameters for Drugs of Abuse Urine (CE) MultiSTAT kit and Drugs of Abuse Blood (CE) MultiSTAT kit have been updated to introduce tighter control ranges for the Reference and Correction checks in the software.

Risk to Health:

The Drugs of Abuse Urine (CE) MultiSTAT kit is used for screening purposes and positive results require further confirmatory analysis. The risk of misreporting of patient results is therefore reduced with low risk to health.

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

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

Action to be taken:

- Review positive results for the above mentioned batches and ensure confirmatory analysis was carried out.
- Complete and return the response form 12187-QA to support@randoxtoxicology.com within five working days.
- Request updated panel parameter version from support@randoxtoxicology.com if you have the affected batch of kit in stock and follow instructions provided to complete the update. Future batches will use the include the updated panel parameters.

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 Toxicology Support.

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

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