RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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Tel: +44 (0) 28 9445 1070

Date Issued: 07 June 2019
Complaint Reference: REC404

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
Assayed Bovine Multi-Sera - Level 1	AL1027	05055273200140	205SL	28 Sep 2022	03 Dec 2018

Reason for Action:

Randox is re-assigning the Mean of all Instruments target and range for Bile Acids (5th Generation Colorimetric) in the Assayed Bovine Multi-Sera Level 1 Control Lot 205SL. Updated value sheets are now available on www.randox.com under Support and Documentation and attached to the email of this contact. No other lots or products are affected by this issue.

Risk to Health:

Quality control results which are not within range may lead to a delay in reporting results. Normal and Elevated Quality Control material will provide verification of patient test results within this concentration range.

Action to be taken:

- Inspect your stock and quarantine affected stock on hand to prevent further use.
- Discard all value sheets and replace these with the value sheets provided.
- A review of previously generated patient results is not required as control failure is evident at the time of testing.
- Discuss the contents of this notice with your Medical Director.
- Complete and return the response form 12187-QA to technical.services@randox.com within five working days.

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

Last printed: 07 June 2019

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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

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