

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: 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.

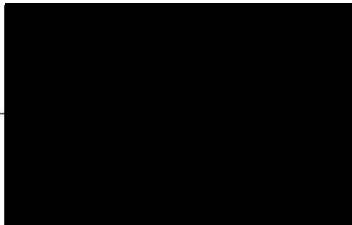
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Transmission of Field Safety Notice: Send a copy of the FSN to all affected customers and to those who need to be aware within your organisation.

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

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



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Please check ALL appropriate boxes.

- ☐ I have read and understand the recall instructions provided in the Field Safety Notice.
- ☐ I have checked my stock and have quarantined the affected kits.
- ☐ I have notified all those who need to be aware of this notice within the organisation.

Indicate disposition of recalled product:

- ☐ no affected stock
- ☐ quarantined pending correction (*specify quantity*);
- ☐ replaced the Value Sheet of the affected lot (*specify quantity*);

Customer Details

Company Name	
Address	

Total Quantity

Received	
Distributed	

Area of Distribution (To be completed by Distributors and Randox Offices)

- ☐ I have identified and notified my customers that were shipped or may have been shipped this product by (*specify date and method of notification*); **OR**
- ☐ Detailed below is a list of customers who received/may have received this product. Please notify my customers. (List of customers may also be sent in a separate attachment)

Have you been notified of any adverse events associated with recalled product?

- ☐ YES
☐ NO

If yes, please explain: _____

Consignee	Country	Quantity Received	Analyser / Kit Serial / Lot Number	Replacements Required

Completed By	Print Name:	Date	
	Signature:		
Contact Telephone			
Contact Email			

Complete and return the response form to technical.services@randox.com within five working days.