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: 18th February 2022

Complaint Reference: REC577

Action Type: Device recall

Detail on Affected Devices:

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

Table 1:

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
Total Bile Acids	BI3863	05055273200720	567619	28th Nov 2022	29th July 2021
Total Bile Acids	BI7982	05055273200737	567595	28th Nov 2022	27th July 2021

Reason for Action:

Randox Laboratories has received an escalation in complaints with regards to atypical low calibration absorbances for the lots listed in Table 1 above. This low calibration absorbance may lead to failed calibration or low end inaccuracy.

Randox can confirm that due to an increase in low end inaccuracy, patient results within the normal reference range of 0 – 10µmol/L may be falsely decreased or increased. (Refer to Table 2 and Figure 1 for Randox's internal testing results).

Therefore, Randox is asking customers to discard the kits listed in Table 1.

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

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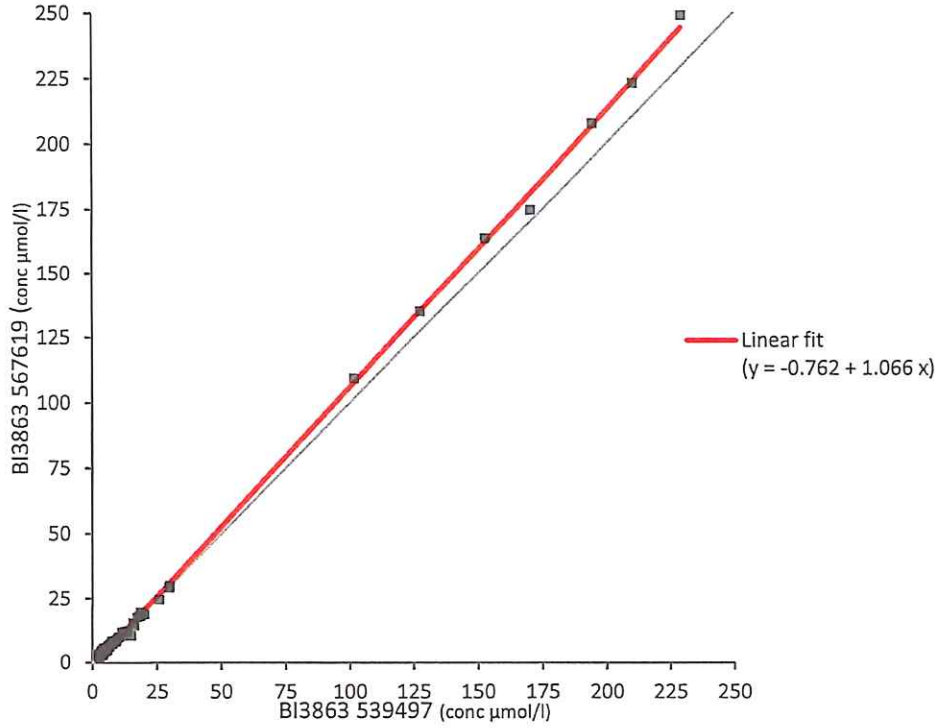
Table 2: Patient Comparison to Reference Lot 539497

Worst Case Negative % Bias	Worst case % Positive Bias
-29.8% at 4.03 µmol/L	+34.6% at 3.53 µmol/L

Figure 1. Patient sample correlation for Impacted batch 567619 comparing results against Reference batch 539497, Linear Regression



Risk to Health:

Total Bile Acids is used as a marker for normal liver function. There is a negligible risk to health for the described issue since the inaccuracy observed would not lead to a clinically significant difference in patient management.

Action to be taken:

- Discontinue use of and discard any of the above batches immediately. Provide photographic evidence of the destruction of any remaining kits.

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- 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.

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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Response Form

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Please complete this form *even if you do not have any affected stock*.

Date Issued: 18 Feb 22
Complaint Reference: REC577 **Action Type:** Product Recall

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
Total Bile Acids	BI3863	05055273200720	567619	28th Nov 2022	29th July 2021
Total Bile Acids	BI7982	05055273200737	567595	28th Nov 2022	27th July 2021

Please check ALL appropriate boxes.

- ❑ I have read and understand the instructions provided in the Field Safety Notice.
- ❑ I have checked my stock and identified the affected kits.
- ❑ I have notified all those who need to be aware of this notice within the organisation.
- ❑ Field Safety Notice is not applicable to my use of the product.

Indicate disposition of affected product:

- ❑ no affected stock
- ❑ destroyed (*specify quantity, date and method*); **Provide photographic evidence of the destruction of remaining kits**

Customer Details

Company Name	
Address	

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Response Form

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Total Quantity

Received	
Distributed	

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

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

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your regulatory authority requires your response form as evidence of the effectiveness of the corrective actions detailed in the FSN.

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PART 2 (To be completed by Distributors and Randox Offices only)

Area of Distribution

- ❑ 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)

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

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

- ❑ YES
- ❑ NO

If yes, please explain: _____