RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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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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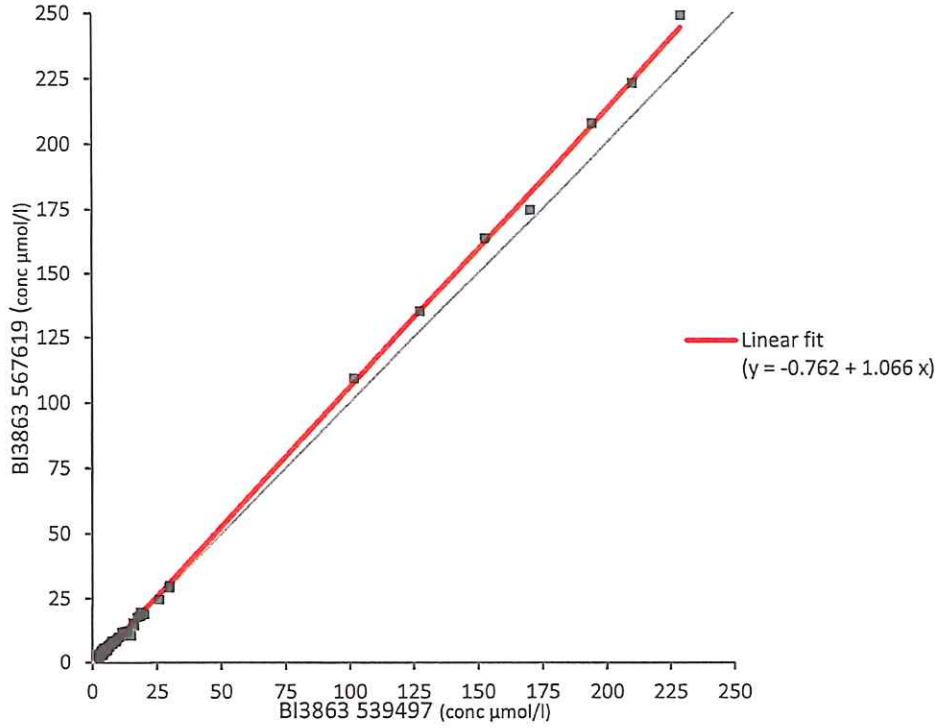
Table 2: Patient Comparison to Reference Lot 539497

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

18 Feb 2022

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