

RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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Date Issued: 11th Oct 2023

Complaint Reference: REC695

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 |
|---------------------------|------------------|----------------|--------------------|
| Total Bilirubin | BR8377 | 05055273214772 | Not Batch Specific |
| Vanadate Oxidation Method | BR9766 | 05055273208337 | Not Batch Specific |
| | BR4061 | 05055273214765 | Not Batch Specific |

Reason for Action:

Randox have had reports of elevated patient results using Plasma (lithium heparin) samples with Total Bilirubin reagent (TBil) Vanadate Oxidation Method catalogue numbers BR4061, BR8377 and BR9766. Randox are currently investigating Plasma (lithium heparin) sample interference with the sample collection and preparation steps. For this reason, the only sample type that is recommended at this time is Serum. Following our investigation, Randox will complete a further customer notice to update our Instructions for Use (IFU).

Risk to Health:

Plasma (lithium heparin) samples giving falsely elevated total bilirubin results. Bilirubin is a waste product from the breakdown of haemoglobin in red blood cells. It is eliminated from the blood by the liver and elevated levels in the blood can be an indicator of liver disease.

Action to be taken:

- Total Bilirubin Vanadate Oxidation Method can only to be used on Serum samples.
- Review results generated with Plasma (lithium heparin) samples in line with the clinical profile of the patient.
- 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

A handwritten signature in black ink, appearing to be 'David Lee', with a long horizontal flourish extending to the right.