RANDOX

Urgent Field Safety Notice

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Date Issued: 26th April 2024

Complaint Reference: REC695 Rev 2

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 Vanadate Oxidation Method	BR8377	05055273214772	Not Batch Specific
	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 can now confirm the investigation is complete and the reagent IFUs have been updated with sample specific Plasma (lithium heparin) interference claims for intralipids. Serum or Plasma (lithium heparin) sample collection and preparation can be recommended for the Total Bilirubin Vanadate Oxidation Method. Updated IFUs are available on www.randox.com and included with this contact. Please discard the previous version and download the updated version.

- **Catalogue Number BR9766**

PLASMA INTERFERENCE
The criteria for no significant interference is recovery within ±10% of the initial value of Total Bilirubin concentration of 16.1 µmol/L (0.940 mg/dL) and 232 µmol/L (15.0 mg/dL).

	16.1 µmol/L	232 µmol/L
Intralipid	143 mg/dL	400 mg/dL

- **Catalogue Number BR4061**

PLASMA INTERFERENCE
The criteria for no significant interference is recovery within ±10% of the initial value of Total Bilirubin concentration of 12.02 µmol/L (0.703 mg/dL) and 232 µmol/L (13.6 mg/dL).

	12.02 µmol/L	232 µmol/L
Intralipid	190 mg/dL	400 mg/dL

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

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- **Catalogue Number BR8377**

PLASMA INTERFERENCE
The criteria for no significant interference is recovery within ±10% of the initial value of Total Bilirubin concentration of 16.1 µmol/L (0.940 mg/dL) and 258 µmol/L (15.1 mg/dL).

	16.1 µmol/L	258 µmol/L
Intralipid	143 mg/dL	750 mg/dL

Physiological changes in serum or plasma analyte concentrations can be caused by a number of substances. The user must remain vigilant to the possible effect on results of unknown interferences from medications or endogenous substances. All patient results must be evaluated in line with the total clinical status of the patient.

Risk to Health:

Plasma (lithium heparin) samples may give 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. Randox IFUs for Total Bilirubin Vanadate Oxidation method have been updated with sample specific Plasma (lithium heparin) intralipid interference claims.

Action to be taken:

- 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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