

RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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Date Issued: 26 November 2018

Complaint Reference: REC 361

Action Type: Device Modification

Detail on Affected Devices: Fructosamine Calibrator (FRUC CAL), Fructosamine Control – Level 1 (FRUC CONTROL 1), Fructosamine Control – Level 3 (FRUC CONTROL 3).

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

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
Fructosamine Calibrator	FR2993	05055273203110	498FR	28 March 2019	28 May 2018
Fructosamine Control 1	FR2994	05055273203127	499FR	28 March 2019	17 May 2018
Fructosamine Control 3	FR2996	05055273203134	500FR	28 March 2019	18 May 2018

Reason for Recall:

Randox is conducting a Device Modification for Fructosamine Calibrator, Fructosamine Control 1 and Control 3 for the lots specified in the table above. The assigned value of Fructosamine in this calibrator and controls has now been re-assigned.

You may observe a negative shift in patient mean by up to 25% with calibrator lot 498FR. Please adjust your current calibrator/control concentration targets with the targets found in the attached Value Sheets.

Risk to Health:

Serum fructosamine levels are elevated in diabetic patients with elevated blood glucose. It provides a shorter-term representation of glycaemic control than HbA1c so is useful for evaluating the effectiveness of medication changes and monitoring the treatment of gestational diabetes. The test is also recommended in situations where HbA1c cannot be reliably measured.

Fructosamine should only be measured as an index of glycaemic control in patients with diabetes. A trend from a normal to a high fructosamine level may indicate that a person's glucose control is not adequate. This, however, does not pinpoint the cause and results must be evaluated in the context of a person's overall clinical findings. The change in recovery with these calibrators is unlikely to have any impact on patient safety as the patient mean remains within the normal range for fructosamine.

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Action to be taken:

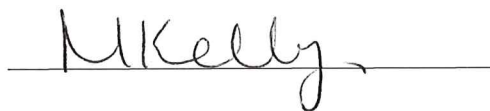
- Please review all remaining stock and add the attached important notice to each kit. Replace the kit value sheet with the revised document provided.
- Discuss the contents of this notice with your Medical Director.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.
- Complete and return the response form 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.

A handwritten signature in black ink, appearing to read 'M. Kelly', is written over a horizontal line.