

RA N D[®]X

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: 05 July 2019

Complaint Reference: REC395

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	Expiry Date	Manufacturing Date
Calibration Serum Level3	CAL2351	05055273200966	961UE	28 Jan 2020	Jan 2018
			995UE	28 July 2020	May/June 2018
			997UE	28 July 2020	July 2018
			1024UE	28 Dec 2020	March 2019
			1055UE	28 May 2021	Dec/ Feb 2019
Bovine Chemistry Assayed	AE1032	05055273200119	-	-	
	AL1027	05055273200140			
	AN1026	05055273200294			
Liquid Assayed Chemistry Control Premium	LAN4216	05055273208993	-	-	-
	LAE4217	05055273209020			
Assayed Chemistry Control Premium Plus	HN1530	05055273203783	-	-	-
	HE1532	05055273203608			

Reason for Action:

Randox have realigned the RX Analyser Series calibration targets by 10% for AST and 9% for ALT in line with the Mean of All Instrument method target from calibrator lot 961UE onwards. With this change a decrease in patient running means may be observed on the RX Series instruments. No other instruments are affected.

The target and range for the associated Quality Control Material has been revised to align with this change. Updated RX control targets are available at randox.com.

Risk to Health:

ALT measurements are used in the diagnosis and treatment of certain liver diseases (e.g. viral hepatitis and cirrhosis) and heart diseases. Critical changes in values are approximately x 3 higher than the upper limit of the normal range.

Elevated levels of AST is a non-specific indicator of tissue damage. Typical intraindividual variation is 16%. Critical changes in values are approximately x 20 higher than the upper limit of the normal range.

The risk to patient health is negligible as the impact of a 10% change in recovery is minimal in the context of observed concentrations of ALT and AST in liver disease.

Action to be taken:

- Replace all Quality Control value sheets with the revised sheets available on www.randox.com.
- 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

.....