RANDOX

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: 18th October 2021

Complaint Reference: REC557

Action Type: Device recall

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
Cholesterol	CH200	05055273201130	559344	28th June 2022	30th April 2021
			572730	28th July 2023	9th Sept 2021

Reason for Action:

Randox Laboratories is conducting a Device Recall for Cholesterol kit CH200, batches 559344 & 572730. The product fails to meet the performance claims quoted on the kit insert.

- **Cholesterol (CHOL) Manual Procedure** when calibrating using the standard provided in the kit, the change in absorbance is lower than expected generating internal quality control results high outside range. See Table 1 below.

Table 1 Example testing completed using manual calculation (Using a standard)

QC Sample	Target Concentration	Range	Kit lot 507208	Kit Lot 559344	% Difference
1369UN	4.02	3.49 – 4.55	3.67	5.76	+57%
1003UE	6.93	6.03 – 7.85	6.68	8.72	+31%

- **Cholesterol (CHOL) Instrument Specific Application** using the recommended calibration material CAL2351, the product fails to meet its linearity performance claim quoted on the kit inserts. The linearity is reduced by up to -35% however Quality Control results will still fall within assigned ranges. See Table 2 below.

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

Randox Laboratories Ltd
55 Diamond Road Crumlin
United Kingdom BT29 4QY
technical.services@randox.com
Tel: +44 (0) 28 9445 1070

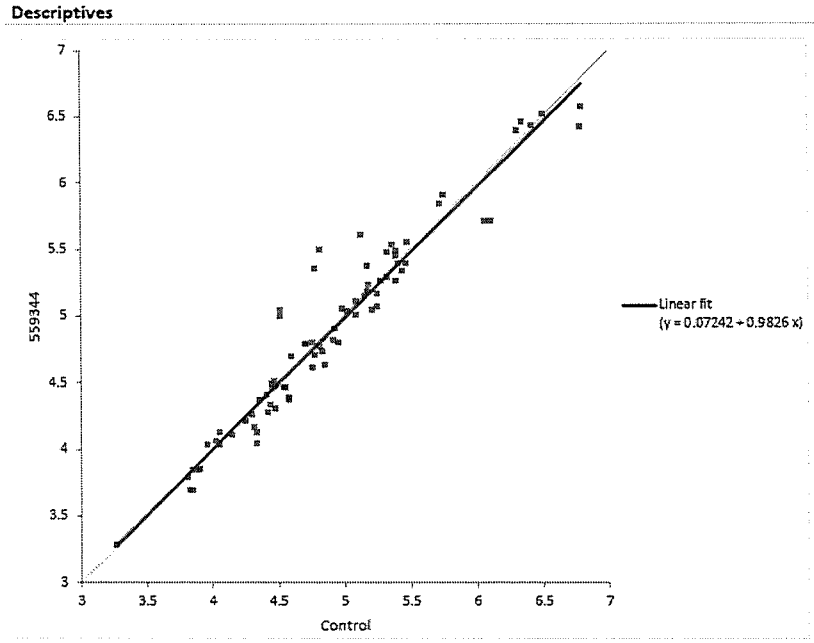
Table 2 Testing completed on Automated Clinical Chemistry instrument

Sample	Concentration (mmol/L)	Control Batch (mmol/L)	Test Batch (mmol/L)	% Difference
Linearity Sample	22.93	22.77	14.71	-35.4%
Human Assayed Serum Level 3	7.06	7.02	6.89	-1.9%
Human Assayed Serum Level 2	4.00	3.99	4.09	+2.5%

Patient Correlation

A limited Cholesterol correlation study comparing patient sample recovery using batch 559344 and a control batch can be seen in Figure 1 below. Figure 1 demonstrates that batch 559344 will have higher than expected variability in recovery but risk of miss-classification is low.

Figure 1. Patient sample correlation for batch 559344 comparing results against a control batch, Linear Regression



Slope	0.983
Y-int	+0.072 mmol/L
R	0.967
Range covered by samples	3.28 - 6.57 mmol/L

Risk to Health:

RANDOX

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

Cholesterol is used in the diagnosis and treatments of lipid and lipoprotein metabolism disorders. The use of CH200 batches 559344 & 572730 may lead to a delay in reporting results due to Quality control results being variable and outside range. Elevated patient samples are not misclassified.

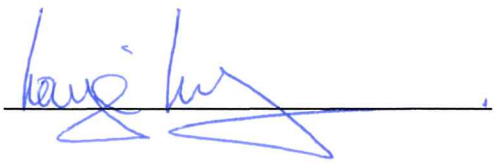
Action to be taken:

- Discontinue use of and discard any of the above batches immediately.
- Review your reagent inventory of these products and assess your laboratories needs for reimbursement for discarded inventory.
- Review results generated with the affected batches 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.

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



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