

Date Issued: 11 December 2019

Complaint Reference: REC430

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
Liquid Clinical Chemistry Control	LAE4217	05055273208993	1021UE	30 Jun 2020	21 Oct 2018

Reason for Action:

A transcription error has occurred for the Radox Lipase colorimetric value in Liquid Clinical Chemistry Control lot 1021UE. The target and range are listed as 50 U/L (40 – 60) and should be 72U/L (58 – 86).

Risk to Health:

Control falling out of range could lead to a delay in reporting patient results. See attached HHE.

Action to be taken:

- Update the affected kits with the correct target values provided.
- Discuss the contents of this notice with your Medical Director.
- Complete and return the response form 12187-QA to technical.services@radox.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 Radox Technical Services.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency


