

Date Issued: 12th September 2024

Complaint Reference: REC756

Action Type: Device Modification

Detail on Affected Devices:

Device Name	Catalogue Number	UDI	Batch / Lot number	Expiry Date	Manufacturing Date
HUMAN ASSAYED MULTI-SERA - LEVEL 2	HN1530	05055273203783	1717UN	28 Mar 28	22 May 24
			1716UN		22 May 24
			1695UN		14 May 24

Reason for Notification:

Randox Laboratories can confirm there has been a transcription error in the Instructions for Use (IFU) for the Human Assayed Control Level 2, HN1530, lots 1717UN, 1716UN & 1695UN for the HDL-Cholesterol method target and range. Please see the correct target value across all 3 lots below. The IFUs have been updated and are available on www.randox.com. Please discard the incorrect IFUs and download the updated IFUs.

Incorrect Targets (1717UN/1716UN/1695UN)					
Analyte	Unit	Target	Low – High	1SD	2SD
HDL- Cholesterol Direct Clearance method	mmol/l	2.53	2.15-2.91	0.190	0.380
	mg/dl	97.7	83.0-112	7.15	14.3
Correct Targets (1717UN/1716UN/1695UN)					
Analyte	Unit	Target	Low – High	1SD	2SD
HDL- Cholesterol Direct Clearance method	mmol/l	1.19	1.01-1.37	0.09	0.18
	mg/dl	45.9	39.0-52.8	3.45	6.90

Action to be taken:

Transmission of Customer Notification: Send a copy of the notification to all affected customers and to those who need to be aware within the organisation.

Complete and return the response form (12187-QA) to technical.services@radox.com within five working days.

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.