

RANDOX
Customer Notification

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Date Issued: 5th April 2024

Complaint Reference: REC738

Action Type: Device Modification

Detail on Affected Devices:

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
Human Assayed Multi-Sera Level 3	HE1532	05055273203608	1257UE	28 th Nov 2025	16 th Mar 2022
			1258UE	28 th Nov 2025	5 th Dec 2022
			1228UE	28 th Nov 2025	8 th Apr 2022
			1247UE	28 th Jan 2026	7 th Dec 2022
			1269UE	28 th Jan 2026	6 th Jun 2022
			1270UE	28 th Jan 2026	8 th Jul 2022
			1195UE	28 th Apr 2025	26 th Nov 2021
			1223UE	28 th Apr 2025	23 rd Sep 2021
			1224UE	28 th Apr 2025	23 rd Sep 2021
			1211UE	28 th Aug 2025	4 th Feb 2022
	1212UE	28 th Aug 2025	23 rd Jun 2022		
	HS2611	05055273203813	1195UE packed into batches 578618, 590845	28 th Jun 2024	27 th Sep 2021
				28 th Mar 2025	23 rd Nov 2021

Reason for Notification:

Radox Laboratories can confirm the analyte NEFA in the above listed lots and packed into the above listed batches has increased over the shelf life of the product and requires the targets and ranges to be reassigned. Please see below table for updated targets and ranges.

The value sheets have been updated and are available on www.radox.com, please discard the previous version and download the updated version.

Catalogue Number	Lot Numbers	Previous Target	Previous Range	Updated Target	Updated Range
HE1532, HS2611	1257UE	0.49	0.39-0.59	0.57	0.46-0.68
	1258UE	0.49	0.39-0.59	0.57	0.46-0.68
	1228UE	0.49	0.39-0.59	0.57	0.46-0.68
	1247UE	0.56	0.45-0.68	0.67	0.54-0.80
	1269UE	0.56	0.45-0.68	0.67	0.54-0.80
	1270UE	0.56	0.45-0.68	0.67	0.54-0.80
	1195UE	0.46	0.37-0.55	0.49	0.39-0.59
	1223UE	0.46	0.37-0.55	0.49	0.39-0.59
	1224UE	0.46	0.37-0.55	0.49	0.39-0.59
	1211UE	0.51	0.41-0.61	0.61	0.49-0.73
	1212UE	0.51	0.41-0.61	0.61	0.49-0.73

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@randox.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 Randox Technical Services.