

# RANDOX

## Customer Notification

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**Date Issued:** 5<sup>th</sup> August 2025

**Complaint Reference:** REC800

**Action Type:** Device Modification

Detail on Affected Devices:

Device Name	Catalogue Number	UDI	Batch / Lot number	Expiry Date	Manufacturing Date
Immunoassay Premium Level 1	IA2638	05055273203844	2275EC	28 <sup>th</sup> May 2026	27 <sup>th</sup> Sep 2023
	IA3109	05055273207255	2269EC	28 <sup>th</sup> May 2026	25 <sup>th</sup> Oct 2023

### Reason for Notification:

Randox Laboratories can confirm that the analyte Thyroid Stimulating Hormone (TSH) in Immunoassay Premium Level 1 lots 2275EC and 2269EC in some methods/analysers is recovering high, outside range. Please contact [technical.services@randox.com](mailto:technical.services@randox.com) if you obtain a high TSH result.

### 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](mailto: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.