

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: 05 Feb 2019

Complaint Reference: REC369

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
Immunoassay Premium	IA2633	05055273207286	440941	28 Apr 2020	11 Jan 2018
	IA2638	05055273203844	1720EC	28 Apr 2020	09 Aug 2017
Immunoassay Premium Plus	IA3109	05055273207255	1714EC	28 Apr 2020	20/21 Sept 2017
	IA3112	05055273207286	430312	28 Apr 2020	22 Sep 2017
	IA3112	05055273207286	432364	28 Apr 2020	13 Oct 2017
Liquid Immunoassay Premium	LIA3105	05055273207200	1723EC	28 Apr 2020	23 Feb 2018

Reason for Recall:

The target value for T uptake on the Siemens Immulite 2000 is incorrect on the value sheet for the products listed above.

The target value for this analyser is listed as 43.8%U and should be 39.4 %U.

Risk to Health:

T uptake is a measure of unbound thyroxine binding globulins in the blood. Unsaturated TBG increases with decreased levels of thyroid hormones. When performed with other thyroid tests it can help diagnose hyperthyroidism and hypothyroidism. T uptake is of little clinical value alone; it is used to determine the Free Thyroxine Index which provides improved but not absolute determination of thyroid function. Should the control value be reported as out of range there may be a delay in reporting test results. However this is unlikely to result in harm to a patient as the T uptake is not a critical biomarker and is run as a panel of thyroid tests.

Action to be taken:

- Replace the value sheets for any remaining stock.
- A review of previous results is not required as controls out of range are investigated at time of occurrence.
- 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.

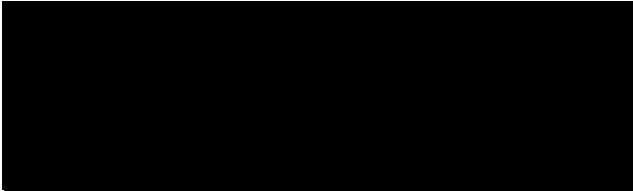
RANDOX
Urgent Field Safety Notice

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

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



Date Issued:

Complaint Reference: REC369

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
Immunoassay Premium	IA2633	05055273207286	440941	28 Apr 2020	11 Jan 2018
	IA2638	05055273203844	1720EC	28 Apr 2020	09 Aug 2017
Immunoassay Premium Plus	IA3109	05055273207255	1714EC	28 Apr 2020	20/21 Sept 2017
	IA3112	05055273207286	430312	28 Apr 2020	22 Sep 2017
	IA3112	05055273207286	432364	28 Apr 2020	13 Oct 2017
Liquid Immunoassay Premium	LIA3105	05055273207200	1723EC	28 Apr 2020	23 Feb 2018

Please check ALL appropriate boxes.

- I have read and understand the recall instructions provided in the Field Safety Notice.
- I have checked my stock and have quarantined the affected kits.
- I have notified all those who need to be aware of this notice within the organisation.

Indicate disposition of recalled product:

- Reworked with the new value sheet (*specify quantity and date*);
- quarantined pending correction (*specify quantity*);

Customer Details

Company Name	
Address	

Total Quantity

Received	
Distributed	

Area of Distribution (To be completed by Distributors and Radox Offices)

- I have identified and notified my customers that were shipped or may have been shipped this product by (*specify date and method of notification*); **OR**
- Detailed below is a list of customers who received/may have received this product. Please notify my customers. (List of customers may also be sent in a separate attachment)

Have you been notified of any adverse events associated with recalled product?

- YES
 NO

If yes, please explain: _____

Consignee	Country	Quantity Received	Device Serial / Lot Number	Replacements Required

Completed By	Print Name:	Date	
	Signature:		
Contact Telephone			
Contact Email			

Complete and return the response form to technical.services@radox.com within five working days.