

RANDOX

Urgent Field Safety Notice

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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.

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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


