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Urgent Field Safety Notice:

IMMULITE® 2000 / IMMULITE® 2000 XPi

– **IMMULITE 2000 Thyroglobulin Not Meeting Claim for Functional Sensitivity**

To whom it may concern,

Our records indicate that your facility may have received the following product:

Table 1. IMMULITE 2000/IMMULITE 2000 XPi Affected Products

Assay	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number	Date of First Distribution (YYYY-MM-DD)	Expiration Date (YYYY-MM-DD)
IMMULITE® 2000 Thyroglobulin	10381648	00630414962252	431	2022-03-24	2023-02-28
			432	2022-03-24	2023-02-28
			433	2022-05-02	2023-04-30
			434	2022-06-09	2023-04-30
			435	2022-07-18	2023-06-30
			436	2022-07-29	2023-07-31

Reason for Correction

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed through customer complaints the potential for Functional Sensitivity to not meet Instructions For Use (IFU) claims with the kit lots listed in Table 1.

Additionally, IMMULITE Thyroglobulin Control Module control level one may result outside of the published ranges. Per good laboratory practice, patient results are not reported when controls result out of range.

When control results are in range, users may observe increased imprecision with low level patient samples. Representative precision data generated during Siemens internal investigation into this issue is shown below in Table 2.

The IMMULITE/IMMULITE 1000 Thyroglobulin assay is not impacted.

Siemens Healthcare Diagnostics is currently investigating the root cause of this issue.

Table 2. IMMULITE 2000 Thyroglobulin Patient Precision Data (20 replicates)

Representative Data for Unaffected Lots			Representative Data for Affected Lots		
Mean Dose (ng/mL)	**Min / Max Dose (ng/mL)**	**CV**	**Mean Dose (ng/mL)**	**Min / Max Dose (ng/mL)**	**CV**
0.300	< 0.2 / 0.500	37.6%	0.235	< 0.2 / 0.777	55.5%
0.983	0.747 / 1.24	15.1%	0.526	< 0.2 / 1.03	50.5%
1.41	1.04 / 1.90	15.9%	1.11	0.674 / 2.00	32.5%
3.37	2.91 / 4.02	7.4%	3.52	2.73 / 5.07	18.4%
6.85	6.13 / 8.32	7.9%	6.81	5.69 / 7.88	8.8%
8.88	8.05 / 9.88	5.9%	9.47	8.43 / 10.5	6.4%
10.2	9.22 / 11.1	4.9%	9.32	7.52 / 10.6	8.8%
32.4	30.7 / 36.9	5.0%	32.8	29.0 / 36.5	5.9%
44.0	40.8 / 47.4	3.9%	43.6	39.9 / 49.7	6.0%
282	258 / 305	4.3%	289	254 / 319	6.5%

Note: Approximate mean doses and CVs were calculated for samples where replicates below the assay range (< 0.2 ng/mL) were observed. 0.2 ng/mL was used in calculations where reported result was < 0.2 ng/mL.

Risk to Health

In a worst-case scenario, an erroneously depressed Thyroglobulin (Tg) result may potentially contribute to altered treatment response classification and follow up. Mitigations would include correlation of Tg results with patient clinical signs and symptoms, risk factors, Thyroglobulin serial testing, anti-Tg and TSH results, as well as imaging studies.

A review of previously generated results is recommended to be considered if patient management may have been adversely affected.

Actions to be Taken by the Customer

- Discontinue use of and discard the Thyroglobulin kit lots listed in Table 1.
- Please review this letter with your Medical Director, including consideration for a review of previously generated results as outlined above in Risk to Health.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens Healthineers for reporting to the authorities.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Signature: *Electronically signed by: Roland Ertl*
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