SIEMENS Healthineers

Urgent Field Safety Notice

IMC23-04.A.OUS

December 2022

IMMULITE® 2000
IMMULITE® 2000 XPi

IMMULITE 2000 Thyroglobulin Not Meeting Claim for Functional Sensitivity

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.

511 Benedict Avenue
Tarrytown, NY 10591

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.

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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.

IMMULITE is a trademark of Siemens Healthcare Diagnostics Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

IMMULITE 2000 Thyroglobulin Not Meeting Claim for Functional Sensitivity

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice IMC23-04.A.OUS dated December 2022 regarding IMMULITE 2000 Thyroglobulin Not Meeting Claim for Functional Sensitivity. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes ☐ No ☐

2. Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes ☐ No ☐

   If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description **Product Catalog #/SMN #/Lot #**	**Quantity of Affected Product in inventory Discarded/ Replacement Quantity Required**
L2KTY2 / 10381648 / 431	
L2KTY2 / 10381648 / 432	
L2KTY2 / 10381648 / 433	
L2KTY2 / 10381648 / 434	
L2KTY2 / 10381648 / 435	
L2KTY2 / 10381648 / 436	

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Customer Sold To #: Customer Ship To #:

Please send a scanned copy of the completed form via email to XXXX@XXXX

Or to fax this completed form to the Customer Care Center at XXXXXX

If you have any questions, contact your local Siemens Healthineers technical support representative.

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