

**IMMULITE® 2000
IMMULITE® 2000 XPI**

Thyroid Stimulating Immunoglobulins (TSI) Kit Lot 389 Negative Patient Bias

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

Table 1. IMMULITE® 2000/IMMULITE® 2000 XPI Affected Product(s)

Assay	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Kit Lot Number	Expiration Date (YYYY-MM-DD)
IMMULITE 2000 and IMMULITE 2000 XPI Thyroid Stimulating Immunoglobulins (TSI)	10713448	(01)00630414597171(10)389(17)221130	389	2022-11-30

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 an average negative bias of -23% with IMMULITE 2000/IMMULITE 2000 XPI Thyroid Stimulating Immunoglobulins (TSI) Assay Kit Lot 389 when compared to other in-date kit lots. The negative bias is observed with patient samples, with concentrations across the assay range and for all sample types indicated in the Instructions for Use (serum, EDTA and lithium heparin plasma). The negative bias is not detected by Quality Control (QC) material. Refer to Table 2 for summary of bias observed during internal testing.

Table 2. IMMULITE 2000/IMMULITE 2000 XPI TSI Assay Kit Lot 389 Results versus Other in-date Kit Lots

TSI sample range	Average Bias	Range of Bias
<0.55 IU/L	-18%	-1% to -50%
≥0.55 to 40 IU/L	-24%	-4% to -46%
Overall average bias across the assay range (0.10 to 40 IU/L)	-23%	See above

This issue is isolated to IMMULITE 2000/IMMULITE 2000 XPI Thyroid Stimulating Immunoglobulins (TSI) Assay Kit Lot 389. Alternate kit lots are available.

Siemens is currently investigating the root cause of this issue.

Risk to Health

When this issue occurs, there is a potential for erroneously depressed patient results. This may lead to a delayed follow up of patients with clinical autoimmune thyroid. Mitigations would include correlation of tests results with additional tests such as anti-TPO antibodies along with thyroid function tests such as total T3 and T4, free T3 and T4 and TSH results. A review of previously generated results is not recommended as results would not be used in isolation.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Discontinue use of and discard the Kit Lot listed in Table 1.
- Review your inventory of this product to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the authorities.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- 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.

IMMULITE is a trademark of Siemens Healthcare Diagnostics Inc.

**IMMULITE 2000 and IMMULITE 2000 XPI Thyroid Stimulating Immunoglobulins (TSI) Kit Lot 389
Negative Patient Bias**

FIELD CORRECTION EFFECTIVENESS CHECK

IMMULITE 2000 and IMMULITE 2000 XPI Thyroid Stimulating Immunoglobulins (TSI) Kit Lot 389 Negative Patient Bias

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice IMC 22-09.A.OUS dated August 2022 regarding IMMULITE 2000 and IMMULITE 2000 XPI Thyroid Stimulating Immunoglobulins (TSI) Kit Lot 389 Negative Patient Bias. 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 SMN # and Lot #	Quantity of Affected Product in inventory Discarded/ Replacement Quantity Required
IMMULITE 2000 and IMMULITE 2000 XPI Thyroid Stimulating Immunoglobulins (TSI) Assay SMN: 10713448 Kit Lot: 389	

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.