

Urgent Field Safety Notice

IMC-15-11.A.OUS

May 2015

IMMULITE[®] 2000
IMMULITE[®] 2000 XPi

Italian Cypress Allergen Shelf-Life Stability

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

Table 1. IMMULITE 2000/IMMULITE 2000 XPi Affected Product

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
Italian Cypress	NA	T23L4	10386079	206, 208

Reason for Recall

Siemens Healthcare Diagnostics has confirmed that the IMMULITE[®] 2000/IMMULITE[®] 2000 XPi Italian Cypress allergen lot 206 does not meet the shelf-life stability as indicated on the label. This may lead to single class change decrease (standard classification) in patient results across the current shelf-life of this allergen lot. Patient dose values may decrease before the stated expiry date listed on the allergen vial.

We anticipate Italian Cypress lot 208 will also not meet its current shelf life stability and must be discarded after June 30, 2015. Customers can continue to use Italian Cypress allergen lot 208 until June 30, 2015.

Siemens is actively investigating this issue in an effort to fully restore the shelf-life stability for the IMMULITE 2000/IMMULITE 2000 XPi Italian Cypress allergen. As a temporary mitigation, future IMMULITE 2000/IMMULITE 2000 XPi Italian Cypress lots may be labeled with a reduced shelf-life.

Risk to Health

In vitro allergen-specific IgE results are not used as a definitive guide for selecting an initial dose for immunotherapy, and an allergic disorder is not based solely on a laboratory result. Factors such as clinical history must be interpreted along with the results of allergen specific IgE testing. Siemens does not recommend a look back if previously generated results of Italian Cypress allergen samples have been run using IMMULITE 2000/IMMULITE 2000 XPi Italian Cypress lots 206 .

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Immediately discontinue use of and discard IMMULITE 2000/IMMULITE 2000 XPi Italian Cypress allergen, lot **206**.

- The shelf-life of IMMULITE 2000/IMMULITE 2000 XPI Italian Cypress allergen, lot 208, has been shortened to June 30, 2015. **Discontinue use and discard lot 208 after June 30, 2015.**
- Please refer to the labeling for each future lot to confirm its expiration date.
- Review your inventory of these products to determine your laboratory's replacement needs.
- Complete and return the Field Correction Effectiveness Check, for IMMULITE 2000/IMMULITE 2000 XPI Italian Cypress allergen **lot 206**, attached to this letter within 30 days.
- Complete and return the Field Correction Effectiveness Check, for IMMULITE 2000/IMMULITE 2000 XPI Italian Cypress allergen **lot 208**, attached to this letter within 30 days, after June 30, 2015.

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 Customer Care Center or your local Siemens technical support representative.

IMMULITE is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Italian Cypress Allergen Shelf-Life Stability **Lot 206**

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice IMC-15-11.A.OUS dated May 2015 regarding IMMULITE 2000/IMMULITE 2000 XPi Italian Cypress Allergen Shelf Life Stability. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number 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 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 that has been discarded	Replacement Quantity Required
T23L4 / 10386079 / Lot 206		

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Customer Sold To #: _____

Customer Ship To #: _____

Please fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.

FIELD CORRECTION EFFECTIVENESS CHECK

Italian Cypress Allergen Shelf-Life Stability **Lot 208**

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice IMC-15-11.A.OUS dated May 2015 regarding IMMULITE 2000/IMMULITE 2000 XPi Italian Cypress Allergen Shelf Life Stability. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

3. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes No
4. Do you now have any of the noted product 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 that has been discarded	Replacement Quantity Required
T23L4 / 10386079 / Lot 208		

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

Please fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.