

Urgent Field Safety Notice

IMC26-04.A.OUS

IMMULITE 2000

IMMULITE 2000 XPi

Title

Potential for Contamination in Mouse Serum Proteins (E76) and Inhalant Panel 4 (IP4) Allergen Vials

Date Issued

Apr-2026

Products

Assay	Test Code	Siemens Material Number Catalog Number Unique Device Identification	Lot Number	Manufacturing Date	Expiration Date
Mouse Serum Proteins Specific Allergen	E76	10385661 E76L2 00630414996585	626	11-Dec-2024	31-Dec-2026
Inhalant Panel 4 Specific Allergen	IP4	10371225 IP4L4 00630414970202	628	29-Oct-2024	31-Oct-2026

Issue Description

Siemens Healthineers has confirmed, through internal investigation, the potential for microbial contamination in IMMULITE 2000 Mouse Serum Proteins (E76) lot 626 and Inhalant Panel 4 (IP4) lot 628 allergen vials.

Based on available data and internal evaluation, no impact to allergen performance has been identified.

Siemens Healthineers is actively investigating the root cause of the issue. The issue is specific to the allergen lots listed in the products table above; all other available allergen lots remain unaffected.

Impact to Results

Based on internal evaluation testing positive and negative samples (using a cutoff of 0.10 kU/L) to compare an affected allergen lot to an unaffected allergen lot, no impact on patient sample results has been identified.

Customer Actions

Perform the instructions provided below:

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
 - Discontinue use of and discard the allergen lots listed in the table above (Products Section).
 - 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.
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- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
 - Please retain this letter with your laboratory records and forward this letter to those who may have received this product.
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**Single Registration
Number (SRN)**

GB-MF-000016339

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.

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Siemens Healthineers

Siemens Healthcare Diagnostics Inc.
333 Coney Street
East Walpole, MA 02032
siemens-healthineers.com

FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice IMC26-04.A.OUS dated Apr-2026. Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1 immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Return this completed form as per the instructions provided at the bottom of this page.

1. Have you read and understood the instructions provided in this letter? Yes ☐ No ☐
2. Do you have the affected product(s) on hand? Please check inventories before answering. Yes ☐ No ☐
3. Were affected Site Personnel notified? Yes ☐ No ☐
4. Was a copy of the letter retained and posted with the current product labeling? Yes ☐ No ☐

If the answer to the question #2 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	
Mouse Serum Proteins Specific Allergen E76L2 / 10385661 / 626		
Inhalant Panel 4 Specific Allergen IP4L4 / 10371225 / 628		
Name of person completing questionnaire:		
Title:		
Institution:		
Street:		
City:	State:	Zip Code:
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

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