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Urgent Field Safety Notice:

IMMULITE® 2000
IMMULITE® 2000 XPi

IMMULITE 2000 and IMMULITE 2000 XPi 3gAllergyTM Specific IgE Potential for False Mold Reactivity

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 Product(s)

Product	Siemens Material Number (SMN)	Kit Lot	UDI	Expiration Date (YYYY-MM-DD)	Date of Manufacture (YYYY-MM-DD)
3gAllergy™ Specific IgE Universal Assay Kit (600T)	10380875	826	(01)00630414962269(10)826(17)20221130	2022-11-30	2021-11-24
		830	(01)00630414962269(10)830(17)20221130	2022-11-30	2021-11-25
		831	(01)00630414962269(10)831(17)20221130	2022-11-30	2021-12-01
		832	(01)00630414962269(10)832(17)20221130	2022-11-30	2021-12-22
		833	(01)00630414962269(10)833(17)20221130	2022-11-30	2022-01-05

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 the potential for falsely elevated specific IgE mold allergen reactivity with quality control material and patient samples when tested using the product listed in Table 1.

Users may observe elevated IMMULITE 2000/IMMULITE 2000 XPi 3gAllergy Specific IgE Negative Quality Control (SMN: 10485107) results outside of the published range (0 - 0.10 kU/L) when tested with the supported panels that contain a mold specific allergen [Mixed Allergen Mold Panel 1 (MP1) and/or Mixed Allergen Inhalant Panel 6 (IP6)] and the kit lots listed in Table 1.

The 3gAllergy Specific IgE Universal Kit Controls are not affected by this issue.

In addition, the potential exists that patient sample results generated with any mold specific allergen and/or mixed allergen panel that contain a mold allergen may show falsely increased IgE reactivity. Siemens' internal investigation showed concentrations up to 0.214 kU/L in patient samples expected to result <0.10 kU/L. All other non-mold allergens and mixed allergen panels that do not contain mold allergen(s) are not affected. This issue is isolated to the kit lots listed in Table 1.

Siemens is currently investigating the root cause.

Risk to Health

This issue has the potential for a patient who is truly negative for an allergen to have a falsely reactive result. Worst case, this may lead to allergen avoidance that is clinically well-tolerated. Mitigations would include correlation of results with clinical signs and symptoms or other additional investigations. A review of previously generated results is not recommended as allergen avoidance is clinically well-tolerated.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Discontinue use of the kit lots 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 product 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
Reason: I am approving this document
Date: Nov 14, 2022 15:52 GMT+1

Email: roland.re.ertl@siemens-healthineers.com

i.A. Roland Ertl, MA
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