

IMMULITE®
IMMULITE® 1000
IMMULITE® 2000
IMMULITE® 2000 XPi

Biotin Interference with the IMMULITE® Systems AlaTOP Allergy Screen Assay

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

Table 1. Affected Product(s)

Assay	Catalog Number	Siemens Material Number (SMN)	Kit Lot Number
IMMULITE/IMMULITE 1000 AlaTOP Allergy Screen	LKAT1	10380869	All lots
IMMULITE 2000/IMMULITE 2000 XPi AlaTOP Allergy Screen	L2KAT2	10380878	All lots

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 has confirmed through internal investigation that the IMMULITE®/IMMULITE® 1000 assay and IMMULITE® 2000/IMMULITE® 2000 XPi assay listed in Table 1 are susceptible to biotin interference. This occurs when biotin, present in patient samples, interferes with the biotin-streptavidin assay architecture on the IMMULITE Systems platform. Biotin interference has the potential to lead to depressed results on the assays listed above. The Instructions for Use (IFU) currently do not list biotin as a potential interferant.

Biotin levels above the concentrations listed in Table 2 can potentially result in interference greater than 10%, leading to falsely depressed results.

Table 2. Biotin Concentration at which ≤10% Bias was Observed

Assay	Biotin Concentration ng/mL (mg/L)
IMMULITE/IMMULITE 1000 AlaTOP Allergy Screen	19 (0.019)
IMMULITE 2000/IMMULITE 2000 XPi AlaTOP Allergy Screen	9 (0.09)

Biotin Interference with the IMMULITE® Systems AlaTOP Allergy Screen Assay

Please refer to the information provided in Table 2 until the appropriate IFU updates regarding biotin interference are completed.

Risk to Health

When this issue occurs, the potential exists for AlaTOP Allergy Screen results near the cutoff to go from reactive to nonreactive which may lead to a possible lack of avoidance to allergen. Mitigations include correlation to clinical signs and symptoms, skin/prick testing, repeat testing and allergen specific IgE testing. Siemens is not recommending a review of previously generated results as it is not feasible to determine which samples contain biotin.

Actions to be Taken by the Customer

- Please refer to the information provided in Table 2 until the appropriate IFU updates regarding biotin interference are completed.
- Please review this letter with your Medical Director.
- 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.

Biotin Interference with the IMMULITE® Systems AlaTOP Allergy Screen Assay

FIELD CORRECTION EFFECTIVENESS CHECK

Biotin Interference with the IMMULITE® Systems AlaTOP Allergy Screen Assay

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice IMC 21-05.A.OUS dated September 2021 regarding Biotin Interference with the IMMULITE® Systems AlaTOP Allergy Screen Assay. 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 ☐

Name of Person Completing Questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

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

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