Siemens Healthcare Diagnostics GmbH, SHS EMEA CEET QT, Siemensstrasse 90,
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Date September 24, 2021

Document Ref# IMC 21-05.A.OUS

Urgent Field Safety Notice:

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

Biotin Interference with the IMMULITE® Systems AlaTOP Allergy Screen Assay

Dear Sirs,

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)

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.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Signature: *Electronically signed by: Roland Ertl Reason: I am approving this document Date: Sep 23, 2021 12:00 GMT+2*

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

i.A. Roland Ertl, MA

Signature: *Electronically signed by: Carina Viehböck Reason: I have reviewed this document Date: Sep 23, 2021 14:17 GMT+2*

Email: carina-marie.viehboeck@siemens-healthineers.com

i.A. DI[in] Carina Viehböck

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Date October 19, 2021

Document Ref# IMC 21-05.B.OUS

Urgent Field Safety Notice:

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

Biotin Interference with the IMMULITE® Systems AlaTOP Allergy Screen Assay

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Reason for Correction

Siemens Healthcare Diagnostics Inc. issued Urgent Field Safety Notice IMC 21-05.A.OUS in September 2021 to inform you of an issue with the product indicated in Table 1 above and provide instructions on actions that your laboratory must take.

As a follow-up, this communication corrects a conversion error of the IMMULITE 2000/ IMMULITE 2000 XPi AlaTOP Allergy Screen assay biotin concentration within Table 2 of IMC 21-05.A.OUS. The mg/L biotin concentration for the IMMULITE 2000/IMMULITE 2000 XPi AlaTOP Allergy Screen assay is the only change between revision A and revision B; all other information remains the same as revision A.

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.

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Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Signature: *Electronically signed by: Roland Ertl Reason: I am approving this document Date: Oct 19, 2021 11:39 GMT+2*

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

i.A. Roland Ertl, MA

Signature: *Electronically signed by: Carina Viehböck Reason: I have reviewed this document Date: Oct 19, 2021 12:21 GMT+2*

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