Urgent Field Safety Notice

PPC25-02.A.OUS

BN II System
BN ProSpec System
Atellica NEPH 630 System
Atellica CH Analyzer
Atellica CI Analyzer

Title N Latex FLC LAMBDA lot 473298/473298A – Incorrect Shelf-Life Information

Date Issued April 2025

Products

Assay	Siemens Material Number/Unique Device Identification	Lot Number	Manufacturing Date	Expiration Date
N Latex FLC LAMBDA	10482438/ 00842768031427	473298 473298A	08-May-2024	07-Nov-2025

Issue Description

Siemens Healthineers has confirmed through internal investigation that N Latex FLC LAMBDA lot 473298 and lot 473298A have an incorrect expiry date printed on the vial label, box label and Siemens Certificate of Analysis (CoA).

It was shown that the shelf-life information is erroneously labeled for 12 months longer than the correct expiry date.

Incorrect expiry date: 07-November 2026

Correct expiry date: 07-November-2025

No other lots of N Latex FLC Lambda currently on the market are affected by this issue.

Impact to Results

If the affected kit lots are used beyond the correct expiry date, QC recovery will indicate the issue, potentially leading to an apparent delay in testing while resolving a QC failure.

Customer Actions

Perform the instructions provided below:

- The affected N Latex FLC LAMBDA lots 473298 and 473298A must not be used after 2025-11-07.

Please review this letter with your Medical Director.

- 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.

Siemens Healthcare Diagnostics Marburg Products GmbH

Emil-von-Behring-Str. 76
D – 35041 Marburg, Germany

SIEMENS Healthineers

Please Note:

- The Siemens CoA has been revised and a correct version is available in the Document Library and attached to this letter.
- For the Atellica NEPH 630 System the expiration date has being corrected on the new Lot Data version from 2025-04.
- For the BN II and BN ProSpec Systems no expiration dates are being displayed within the software.
- For the Atellica CH and Atellica CI analyzer, the reagent must be transferred into Atellica CH EMPTY P1 and manually identified, therefore please use the correct expiration date (2025-11-07).

Single Registration Number (SRN)

DE-MF 000005039

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,

This letter was created electronically and is valid without signature.

i.V. [redacted]
Director
Quality Systems & Compliance

i.A. [redacted]
Marketing Manager
Global Marketing

Attachment 1: Revised Certificate of Analysis for N Latex FLC LAMBDA lots 473298

Attachment 2: Revised Certificate of Analysis for N Latex FLC LAMBDA lot 473298A

Siemens Healthcare Diagnostics Marburg Products GmbH

Emil-von-Behring-Str. 76
D – 35041 Marburg, Germany

FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice PPC25-02.A.OUS dated April 2025. 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.	Were affected Site Personnel notified?	Yes ☐	No ☐
3.	Was a copy of the letter retained and posted with the current product labeling?	Yes ☐	No ☐

Name of person completing questionnaire:			
Title:			
Institution:			
Street:			
City:		**State:**	**Zip Code:**
Phone:		**Country:**	

Please send a scanned copy of the completed form via email to **XXXX@XXXX** [for the OUS letter the information will be filled in by the region].

Or to fax this completed form to the Customer Care Center at **XXXXXX** [for the OUS letter the information will be filled in by the region].

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.

Siemens Healthcare Diagnostics Marburg Products GmbH

Emil-von-Behring-Str. 76
D – 35041 Marburg, Germany

Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany

Customer
To whom it may concern

Certificate of Analysis

P.O.

Material: 10482438	Commission-No.
Kit-Lot: 473298	Customer-Order-No.
Total lot size: 791 PC	Customer-No.
Delivery amount:	Storage at: + 02℃ to 08℃
Release date: 2024-11-08	
Manufacturing date: 2024-05-08	Expiration date: 2025-11-07
Legal Material Number: OPJB035	
Released by: Stefan Barth	

Material: **10482438**
N Latex FLC lambda
Inspection ID-No.: **400000743152**

Kit components:

Level	Material-No. Material-Name	Lot	Release date
0010	11523525 N Latex FLC lambda	473298	2024-11-07

Material: **10482438**
N Latex FLC lambda
Inspection ID-No.: **400000743152**

Inspection results:

Material-No.	**Lot**
11523525 N Latex FLC lambda	**473298**

Sensitivity
The difference of absorbance between a specific protein concentration (see remark) must exceed the required lower limit, if it is compared with the blank value.

	Result Unit	**Assigned Value**	**Upper Limit**	**Lower Limit**
	154 Bit	-	-	70 Bit
Inspection remark	Protein concentration: 1,8 mg/L			

Specificity
Recoveries of known concentration samples should be within the range of the given upper and lower limit.

N FLC Control SL1

	Result Unit	**Assigned Value**	**Upper Limit**	**Lower Limit**
	12.7 mg/l	12.1 mg/l	13.9 mg/l	10.3 mg/l
Inspection remark	lot 473580			

Recovery from target value

	Result Unit	**Assigned Value**	**Upper Limit**	**Lower Limit**
	105 %	-	120 %	80 %
Inspection remark	lot 473580			

N FLC Control SL2

	Result Unit	**Assigned Value**	**Upper Limit**	**Lower Limit**
	32.1 mg/l	33.5 mg/l	38.5 mg/l	28.5 mg/l
Inspection remark	lot 473680			

Recovery from target value

Material: **10482438**
N Latex FLC lambda
Inspection ID-No.: **400000743152**

Material-No.	**Lot**
11523525 N Latex FLC lambda	**473298**

	Result	**Unit**	**Assigned Value**	**Upper Limit**	**Lower Limit**
	96	%	-	120 %	80 %

Inspection remark lot 473680

Internal QC Control

	Result	**Unit**	**Assigned Value**	**Upper Limit**	**Lower Limit**
	30.2	mg/l	30.6 mg/l	35.2 mg/l	26.0 mg/l

Inspection remark lot 473475

Recovery from target value

	Result	**Unit**	**Assigned Value**	**Upper Limit**	**Lower Limit**
	99	%	-	120 %	80 %

Inspection remark lot 473475

Reproducibility
When known concentration samples are assayed 3 times within run, CV has to be within the range of the given upper limit.

N FLC Control SL1

	Result	**Unit**	**Assigned Value**	**Upper Limit**	**Lower Limit**
	0.80	%	-	6.00 %	-

Inspection remark lot 473580

N FLC Control SL2

	Result	**Unit**	**Assigned Value**	**Upper Limit**	**Lower Limit**
	1.40	%	-	6.00 %	-

Inspection remark lot 473680

Internal QC Control

	Result	**Unit**	**Assigned Value**	**Upper Limit**	**Lower Limit**
	0.60	%	-	6.00 %	-

Inspection remark lot 473475

This document was generated by means of electronic data system, which was designed and validated to comply with the FDA21 CFR Part 11 electronic records and signature. This document indicates an electronic signature for batch release.
This lot has been tested and approved for release and shipment by the responsible legal manufacturer Quality department.

[redacted]

COA Verification

[redacted] / Quality Assurance

Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany

Customer
To whom it may concern

Certificate of Analysis

P.O.

Material:
10482438

Commission-No.

Kit-Lot:
473298A

Customer-Order-No.

Total lot size:
865 PC

Customer-No.

Delivery amount:

Storage at:
+ 02℃ to 08℃

Release date:
2024-11-22

Manufacturing date:
2024-05-08

Expiration date:
2025-11-07

Legal Material Number:
OPJB035

Released by:
Stefan Barth

Material: **10482438**
N Latex FLC lambda
Inspection ID-No.: **400000745044**

Kit components:

Level	Material-No. Material-Name	Lot	Release date
0010	11523525 N Latex FLC lambda	473298	2024-11-07

Material: **10482438**
N Latex FLC lambda
Inspection ID-No.: **400000745044**

Inspection results:

Material-No.	Lot
11523525 N Latex FLC lambda	**473298**

Sensitivity
The difference of absorbance between a specific protein concentration (see remark) must exceed the required lower limit, if it is compared with the blank value.

	Result Unit	Assigned Value	Upper Limit	Lower Limit
	154 Bit	-	-	70 Bit
Inspection remark	Protein concentration: 1,8 mg/L			

Specificity
Recoveries of known concentration samples should be within the range of the given upper and lower limit.

N FLC Control SL1

	Result Unit	Assigned Value	Upper Limit	Lower Limit
	12.7 mg/l	12.1 mg/l	13.9 mg/l	10.3 mg/l
Inspection remark	lot 473580			

Recovery from target value

	Result Unit	Assigned Value	Upper Limit	Lower Limit
	105 %	-	120 %	80 %
Inspection remark	lot 473580			

N FLC Control SL2

	Result Unit	Assigned Value	Upper Limit	Lower Limit
	32.1 mg/l	33.5 mg/l	38.5 mg/l	28.5 mg/l
Inspection remark	lot 473680			

Recovery from target value

Material: **10482438**
N Latex FLC lambda
Inspection ID-No.: **400000745044**

Material-No.	**Lot**
11523525 N Latex FLC lambda	**473298**

	Result	**Unit**	**Assigned Value**	**Upper Limit**	**Lower Limit**
	96	%	-	120 %	80 %

Inspection remark lot 473680

Internal QC Control

	Result	**Unit**	**Assigned Value**	**Upper Limit**	**Lower Limit**
	30.2	mg/l	30.6 mg/l	35.2 mg/l	26.0 mg/l

Inspection remark lot 473475

Recovery from target value

	Result	**Unit**	**Assigned Value**	**Upper Limit**	**Lower Limit**
	99	%	-	120 %	80 %

Inspection remark lot 473475

Reproducibility
When known concentration samples are assayed 3 times within run, CV has to be within the range of the given upper limit.

N FLC Control SL1

	Result	**Unit**	**Assigned Value**	**Upper Limit**	**Lower Limit**
	0.80	%	-	6.00 %	-

Inspection remark lot 473580

N FLC Control SL2

	Result	**Unit**	**Assigned Value**	**Upper Limit**	**Lower Limit**
	1.40	%	-	6.00 %	-

Inspection remark lot 473680

Internal QC Control

	Result	**Unit**	**Assigned Value**	**Upper Limit**	**Lower Limit**
	0.60	%	-	6.00 %	-

Inspection remark lot 473475

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COA Verification

[redacted] / Quality Assurance