

Urgent Field Safety Notice

BR-01117_OUS

December 2016

N Latex HCY and N Latex HCY (BCS[®] XP)

Lot 802907632 does not meet once-opened and on-board stability claims

Dear valued customer,

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

Table 1. Affected Product(s)

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number
N-Latex HCY	OPAX032	10445973	802907632
N-Latex HCY (BCS [®] XP)	OPAX055	10482436	802907632

Reason for Urgent Field Safety Notice

Siemens Healthcare Diagnostics has observed a reduced once-opened stability and a reduced on-board stability for the affected lot that may result in erroneously reduced or elevated homocysteine.

This stability issue may lead to a higher than expected lot-to-lot variation and an impaired product performance.

Risk to Health

There is a low health risk based on the issue.

The severity rating for this assay is minor, as the analyte itself indicates a modest correlation to relevant health disorders (e.g. long-term risk marker to thrombosis, stroke, cardiovascular disease, neurological disorders) and the therapeutic regimes relates to vitamin supplementation and to recommendations in nutrition and life-style behavior.

Based on the Siemens assessment, a look-back procedure is not recommended as the analyte homocysteine varies with physiological (increase of HCY due to methionine-rich food) and preanalytical conditions (e.g. duration of storage: HCY increases 10% each hour, if remaining on cruor) as well as sample collection tubes and some medication interferences. Homocysteine levels need to be interpreted in conjunction with other clinical and laboratory informations and should be repeated in certain time intervals (depending on the individual risk and current national and/or expert/advisory panel recommendations).

N Latex HCY and N Latex HCY (BCS[®] XP)

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Actions to be Taken by the Customer

Please discontinue use of and discard the kit lots listed in Table 1.

Complete and return the Field Correction Effectiveness Check/Product Replacement Form attached to this letter within 30 days.

Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the authorities.

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 Customer Care Center or your local Siemens technical support representative.

Sincerely yours,

[Redacted signature block]

[Redacted signature block]

BCS is a trademark of Siemens Healthcare Diagnostics Products GmbH

N Latex HCY and N Latex HCY (BCS® XP)

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FIELD CORRECTION EFFECTIVENESS CHECK

**N Latex HCY and N Latex HCY (BCS® XP)
Lot 802907632 does not meet once-opened and on-board stability claims**

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice BR-01117 dated December 2016 regarding "N Latex HCY and N Latex HCY (BCS® XP) - Lot 802907632 does not meet once-opened and on-board stability claims". Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number 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
2. Do you now have any of the noted product on hand? Please check inventories before answering. Yes No

If the answer to the question 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 that has been discarded	Replacement Quantity Required
N Latex HCY; SMN 10445973, Lot 802907632		
N Latex (BCS®XP) ; SMN 10482436, Lot 802907632		

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Customer Sold To #: _____

Customer Ship To #: _____

Please fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.