

Urgent Field Corrective Action

BR-03416

May 2016

BN II[®], BN ProSpec[®] and BCS[®]-XP Systems

N Latex HCY / N Latex HCY (BCS[®] XP) reagent with reduced once-opened stability

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	OPAX03	10445973	802903488 802905119
N Latex HCY (BCS [®] XP)	OPAX05	10482436	802903488 BCS 802905119 BCS

Reason for Corrective Action

Siemens Healthcare Diagnostics has confirmed that the reagent lots mentioned in Table 1 show a reduced stability once opened that does not meet the claimed time frame. As a consequence QC recoveries can be found below the assigned ranges, giving invalid runs that may prompt customers to a new calibration.

Risk to Health

QC and patient samples may show a lower precision based on the reduced stability once opened. The magnitude of the effect has been assessed as neither being likely to affect patient management of vitamin deficiencies nor will it impact the detection of patients with overt homocysteinuria that typically have plasma concentrations greater than eight to tenfold of the reference interval. Due to this, it is not necessary to review previous test results or to repeat testing.

Actions to be Taken by the Customer

Please discontinue use of the affected lots referenced in Table 1 and discard any remaining inventory.

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Please review your inventory of these products 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 attached to this letter within 30 days.

Please review this letter with your Medical Director.

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,

Dr. Norbert Dedner
Director Quality Systems & Compliance

Dr. Christian Mirwaldt
Global Marketing Plasma Proteins

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FIELD CORRECTION EFFECTIVENESS CHECK

BN[®] II, BN ProSpec[®] and BCS[®]-XP Systems

N Latex HCY / N Latex HCY (BCS[®] XP) reagent with reduced once-opened stability

This response form is to confirm receipt of the enclosed Siemens Healthcare Urgent Field Corrective Action BR-03416 dated May 2016 regarding N Latex HCY / N Latex HCY (BCS[®] XP) reagent with reduced once-opened stability. 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 [Letter Type] 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 802903488 or lot 802905119.		
N Latex HCY (BCS [®] XP), SMN 10482436; Lot 802903488 BCS or 802905119 BCS.		

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.