

Urgent Field Corrective Action

BR-5016_OUS

August 2016

N Latex ASL

Potential calibration issue and sedimentation observed

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)	Kit Number
N Latex ASL	OPBU035, OPBU055	10445983 10445984	110749, 110749A 110749B, 110749C

Reason for Correction

Siemens Healthcare Diagnostics has received complaints from customers not being able to establish a calibration curve or to validate an established calibration curve with the respective controls when using one of the affected lots of N Latex ASL.

The issue could be confirmed for some vials of the affected lots as summarized in Table 1.

Risk to Health

The issue might lead to the inability to calibrate the assay or to invalid test runs. Based on our investigations we do not have any indication that patient results are affected.

Actions to be Taken by the Customer

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

Please complete and return the Field Correction Effectiveness Check 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 review this letter with your Medical Director.

N Latex ASL - Potential calibration issue and sedimentation observed

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,

Original signature is on file

[Redacted signature]

Original signature is on file

[Redacted signature]

FIELD CORRECTION EFFECTIVENESS CHECK

N Latex ASL - Potential calibration issue for some reagent lots

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Corrective Action Letter BR-05016 dated August 2016 regarding N Latex ASL - Potential calibration issue and sedimentation observed.

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 Customer Notification 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 ASL Please specify Lot number affected: _____		

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