

N Latex β 2-Microglobulin

Potential calibration issue for some reagent lots

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 β 2-Microglobulin	OQWU155	10446161	44696, 44800, and 44834
	OQWU215	10446162	44697

Reason for Urgent Field Safety Notice

Siemens Healthcare Diagnostics has received complaints from customers that they were not able to calibrate or validate a test run using one of the affected lots of N Latex β 2-Microglobulin.

The issue could be confirmed internally 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 obtain invalid test runs. However, patient results are not affected. Siemens Healthcare Diagnostics is not recommending a review of previously generated results due to this issue.

Actions to be Taken by the Customer

- Please discontinue use of and discard the affected lots listed in Table 1.
- Complete and return the Product Replacement Form attached to this letter within 30 days.

N Latex β 2-Microglobulin - Potential calibration issue for some reagent lots

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

Original signature is on file

Dr. Norbert Dedner
Director Quality Systems & Compliance

Dr. Claus Prümper
Director Global Marketing Plasmaproteins

N Latex β 2-Microglobulin - Potential calibration issue for some reagent lots

FIELD CORRECTION EFFECTIVENESS CHECK

N Latex β 2-Microglobulin - Potential calibration issue for some reagent lots

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice BR-05415 dated July 2015 regarding N Latex β 2-Microglobulin - Potential calibration issue for some reagent lots.

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 β 2-Microglobulin 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.