

### N Latex $\beta$ 2-Microglobulin

#### Potential calibration issue for some reagent lots

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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 $\beta$ 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  $\beta$ 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.

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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*

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Dr. Norbert Dedner  
Director Quality Systems & Compliance

Dr. Claus Prümper  
Director Global Marketing Plasmaproteins

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**FIELD CORRECTION EFFECTIVENESS CHECK**

N Latex  $\beta$ 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  $\beta$ 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.

REF: PP 15-004 [C/3224]

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2. Do you now have any of the noted product on hand? Please check inventories before answering.  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.	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory that has been discarded	Replacement Quantity Required
N Latex $\beta$ 2-Microglobulin Please specify Lot number affected: _____		

Name of person completing questionnaire:	
Title:	
Institution:	Instrument Serial Number:
Street:	
City:	Post Code:
Phone:	Email:
Customer Sold To #:	Customer Ship To #:

**It is important that your organisation takes the actions detailed in the FSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to this FSN. Your organisations reply is evidence which, Siemens Healthcare, and subsequently the HPRA, needs to monitor the progress of the FSN. Without your reply Siemens Healthcare cannot verify the completeness of the FSN and the HPRA may need to issue a Medical Device Alert.**

Please return this completed FC Effectiveness form within 14 days to:

FAX: 016297401 or EMAIL: CruinnFSNGroup@cruinn.ie