Urgent Field Corrective Action

PP-20-002 A OUS

February 2020

BN ProSpec® System
BN II™ System
Atellica® NEPH 630 System

N Latex CDT Kit – negative bias of %CDT values during shelf-life observed

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

Table 1. BN ProSpec System, BN II System and Atellica NEPH 630 System Affected Product(s)

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Kit Lot Number	Expiration Date (YYYY-MM-DD)	Manufacturing Date (YYYY-MM-DD)
N Latex CDT	%CDT	OPCS03	10445996	49729 49849 49985 50084	2020-04-11	2018-10-12

Reason for Correction

Siemens Healthcare Diagnostics has observed a negative bias for the carbohydrate-deficient transferrin (CDT) measurement when using the affected N Latex CDT Kit lots in comparison to the HPLC method (refer to Table 1). All affected kit lots contain reagents from the same bulk. The issue has been internally observed during performed shelf-life monitoring after 15 months.

CDT results in absolute concentrations may be influenced by patient's transferrin levels and, therefore, results are reported as a ratio of CDT to total transferrin, called %CDT.

As the transferrin determination with N Antiserum to Human Transferrin is not affected, the observed effect leads to calculated %CDT values that show a negative bias of approximately 15% compared to the HPLC method. This could result in a shift of weak positive patient samples into the reference range of 1.19 – 2.47 %CDT which was derived from a study population of healthy adults.

Risk to Health

The overall risk to health is negligible. As this test may help to detect chronic alcohol consumption, there is no direct impact on therapeutic decisions or patient health. It is not expected that samples from patients with chronic heavy alcohol consumption are affected by this issue and that they are misclassified.

In case of moderate chronic alcohol consumption, values may drop within an intermediate zone (grey zone). %CDT is optimized towards a high specificity (exclusion criteria), but moderate sensitivity.

For monitoring purposes, serial measurements of the analyte %CDT are necessary. Especially in moderate-alcohol abuse (including sporadic binge drinkers), it is recommended to include other biomarkers in the assessment. No single or isolated result of this test will be used for a clinical assessment. Therefore, a look-back testing is not required.

The combination of different biomarkers is the best approach to optimize clinical sensitivity and specificity to cover different time periods and different clinical indications/issues.

Actions to be Taken by the Customer

Please review this letter with your Medical Director.

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

Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens Healthineers 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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Sincerely yours,

This letter was created electronically and is valid without signature.

i. V. Dr. Norbert Dedner	i. A. Dr. Lenard Müller
Senior Director	Marketing Manager
Quality Systems & Compliance	Global Marketing Plasma Proteins

FIELD CORRECTION EFFECTIVENESS CHECK

N Latex CDT Kit – negative bias of %CDT values during shelf-life observed

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Medical Device Recall PP-20-002 dated February 2020 regarding Latex CDT Kit – negative bias of %CDT values during shelf-life observed. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the Urgent Medical Device Recall instructions provided in this letter. Yes ☐ No ☐

2. Do you now have any of the noted product(s) 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 Discarded/ Replacement Quantity Required**
N Latex CDT, SMN 10225996, Lot 49729	
N Latex CDT, SMN 10225996, Lot 49985	
N Latex CDT, SMN 10225996, Lot 49849	
N Latex CDT, SMN 10225996, Lot 50084	

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Customer Sold To #: Customer Ship To #:

Please send a scanned copy of the completed form via email to XXXX@XXXX (**for the US ONLY letter** use the following e-mail address: uscctsfcaecfax.team@siemens-healthineers.com, **for the OUS letter** the information will be filled in by the region).

Or to fax this completed form to the Customer Care Center at XXXXXX (**For US ONLY letter,** use the following phone number: (312) 275-7795, **for the OUS letter** the information will be filled in by the region) delete the Not Applicable text in yellow prior to sending.
If you have any questions, contact your local Siemens Healthineers technical support representative.