SIEMENS Healthineers

Siemens Healthcare
Diagnostics Products GmbH

Urgent Field Corrective Action

PP-18-002.A.OUS

May 2018

N Latex CDT

Negative bias of %CDT values

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	Manufacturing Date	Expiration Date
N Latex CDT	OPSC03	10445996	47167	2017-03-14	2018-06-15
			47168	2017-04-06	
			47430	2017-06-01	
			47431	2017-06-09	
			47433	2017-06-27	
			47597	2017-08-02	2018-11-30
			47642	2017-09-04	
			47727	2017-10-05	
			47848	2017-11-06	
			48013	2017-09-22	2019-03-21
			48014	2017-09-22	
			48118	2017-09-22	
			48169	2017-09-22	

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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 lots in comparison to the HPLC method (refer to Table 1).

CDT results in absolute concentrations may be influenced by patient's transferrin levels and, therefore, results are reported as 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

For the products listed in Table 1, please perform the following steps:

Siemens Healthcare Diagnostics has assigned optimized values to the affected lots of standards and controls included in the kit lots (refer to Table 1). Those lots of standards and controls can be used with the revised assigned values and acceptance ranges.

Therefore, please proceed as follows:

- Recalibrate your CDT method with N CDT Standard lots listed in Table 2, using the revised assigned values provided in Table 2.
- Use the revised assigned values and respective ranges of the N CDT Controls provided in Table 2.

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Table 2. Corrected CDT Target values and Acceptance Ranges

Product	Lot	Expiry date		Assigned value	Acceptance ranges (mg/L)		
N CDT Standard	110440	2018-06-15	CDT	386 mg/L	n/a		
N CDT Control 1	110540	2018-06-15	CDT	60.2 mg/L	48.2	to	72.2
			%CDT	1.96	n/a		
			Transferrin content	3.07 g/L			
N CDT Control 2	110640	2018-06-15	CDT	186 mg/L	149	to	223
			%CDT	6.02	n/a		
			Transferrin content	3.09 g/L			
N CDT Standard	110441	2018-11-30	CDT	376 mg/L	n/a		
N CDT Control 1	110541	2018-11-30	CDT	68.0 mg/L	54.4	to	81.6
			%CDT	2.26	n/a		
			Transferrin content	3.01 g/L			
N CDT Control 2	110641	2018-11-30	CDT	185 mg/L	148	to	222
			%CDT	6.02	n/a		
			Transferrin content	3.07 g/L			
N CDT Standard	110442	2019-03-21	CDT	374 mg/L	n/a		
N CDT Control 1	110542	2019-03-21	CDT	62.5 mg/L	50.0	to	75.0
			%CDT	1.96	n/a		
			Transferrin content	3.19 g/L			
N CDT Control 1	110642	2019-03-21	CDT	190 mg/L	152	to	228
			%CDT	5.97	n/a		
			Transferrin content	3.19 g/L			

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- For BN ProSpec and Atellica NEPH 630 customers, a new Lot Data CD as well as new Secure Download Files are expected to be available in June 2018 including the revised CDT target values for N CDT Standard, N CDT Control 1 and N CDT Control 2.
- Please make sure that the values, you manually entered according to this information, are not overwritten by using an older Lota Data CD/Secure Download File afterwards.
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with N Latex CDT determination using the products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens technical support representative.

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,

i. V. Dr. Norbert Dedner
Sr. Director
Quality Systems & Compliance

i. A. Dr. Lenard Mueller
Marketing Manager
Global Marketing Plasma Proteins

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FIELD CORRECTION EFFECTIVENESS CHECK

N Latex CDT
-Negative bias of %CDT values

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Corrective Action Letter PP-18-002.A.OUS dated May 2018 regarding “N Latex CDT – Negative bias of %CDT values”.

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 Corrective Action instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

To fax this completed form please send it to the Customer Care Center at (###) ###-#### or please send a scanned copy of the completed form via email to xxxx. If you have any questions, contact your local Siemens technical support representative.