SIEMENS

Urgent Field Corrective Action

BR-03817_OUS

May 2017

N Antiserum to Human Ceruloplasmin
- Negative bias with N Protein Standard SL and N/T Protein Controls SL

Dear Valued Customer,

Our records indicate that your facility may have received the following product for Human Ceruloplasmin determination:

Table 1. Affected Product(s)

Assay	Product Code	Siemens Material Number (SMN)	Lot Number	Expiration Date
N Protein Standard SL	OQIM13	10446073	083611A, 083611B, 083611C, 083611D	2017-07-11
			083612, 083612A, 083612B	2017-10-14
			083614A, 083614B, 083614C	2018-01-27
			083615, 083615A, 083615B, 083615C	2018-04-11
			083616B, 083616C, 083616D	2018-07-30
N/T Protein Control SL/L	OQIN13	10446076	084647, 084647B, 084647D, 084647E, 084647F	2017-09-13
			084648A, 084648B, 084648D, 084648E, 084648F,084648G	2018-04-30
N/T Protein Control SL/M	OQIO13	10446082	084749, 084749A, 084749B, 084749C, 084749E,084749F	2017-09-17
			084750A, 084750C, 084750D, 084750F, 084750G	2018-02-03
N/T Protein Control SL/H	OQIP13	10446086	084847, 084847C, 084847D, 084847E, 084847F	2017-06-13
			084848, 084848B, 084848C, 084848F, 084848G,084848K	2017-12-17
			084849A, 084849B, 084849F	2018-07-04

Emil-von-Behring Strasse 76
D – 35041 Marburg, Germany

Reason for Correction

Siemens Healthineers has confirmed a negative bias of approximately -20% for results obtained with N Antiserum to Human Ceruloplasmin when calibrating Ceruloplasmin with N/T Protein Standard SL lots listed in Table 1. N/T Protein Controls SL for Ceruloplasmin are similarly biased.

A deviation in the value assignment of the affected standards and controls is leading to a lower result compared to correctly assigned standards.

Note: N Antiserum to Human Ceruloplasmin (REF OUIE) works as intended.

Risk to Health

Patient samples with a true Ceruloplasmin value of up to +20% above the lower end of the reference interval may be incorrectly found below the reference interval.

The overall risk to health is negligible. Abnormal Ceruloplasmin values need to be resolved and would trigger further laboratory and clinical investigations. Results of the test should always be interpreted in conjunction with the patient's history, clinical presentations and other findings.

Actions to be Taken by the Customer

Siemens Healthineers has assigned correct values to those lots of standards and controls where sufficient material was available for a new value assignment. Those lots of standards and controls can be used for determination of Ceruloplasmin with the revised assigned values and acceptance ranges.

Therefore, please proceed as follows:

- Recalibrate your Ceruloplasmin method with N Protein Standard SL lots listed in Table 2, using the values provided in Table 2.
- Use N/T Protein Control SL ranges listed in Table 2 for Ceruloplasmin ranges provided in Table 2.
- Do not use those N/T Protein Control SL and N Protein Standard SL lots listed Table 1 for Ceruloplasmin measurements where NO new assigned values are given in Table 2.

Table 2. Corrected Ceruloplasmin Target Values and Acceptance Ranges

Product	Product code/Ref	Lot and all suffixes	Expiry date	Assigned value (g/L)	Acceptance ranges (g/L)		
N Protein-Standard SL	OQIM	083615	2018-04-11	0.388	n/a		
		083616	2018-07-30	0.354	n/a		
N/T Protein-Control SL/L	OQIN	084647	2017-09-13	0.247	0.21	to	0.284
		084648	2018-04-30	0.271	0.23	to	0.312
N/T Protein-Control SL/M	OQIO	084749	2017-09-17	0.423	0.36	to	0.486
		084750	2018-02-03	0.416	0.354	to	0.478
N/T Protein-Control SL/H	OQIP	084848	2017-12-17	0.508	0.432	to	0.584
		084849	2018-07-04	0.528	0.449	to	0.607

Note: Bottle Values Assignments (BVA) for all other analytes are not affected.

- A new Lot Data CD is expected to be available in May 2017 including the corrected Ceruloplasmin target values for N Protein Standard SL and N/T Protein Controls SL/L, SL/M, SL/H.
- New Secure Download Files is expected to be available in May 2017 including the corrected Ceruloplasmin target values for the N Protein Standard SL and N/T Protein Controls SL/L, SL/M, SL/H.
- In case that you have changed the assigned values manually, please make sure that these values are not overwritten by using a Lota Data CD/Secure Download File of March 2017 or before.
- 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 Ceruloplasmin 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. Christian Mirwaldt
Marketing Manager
Global Marketing Plasma Proteins

Emil-von-Behring Strasse 76
D – 35041 Marburg, Germany

FIELD CORRECTION EFFECTIVENESS CHECK

N Antiserum to Human Ceruloplasmin
- Negative bias with N Protein Standard SL and N/T Protein Controls SL

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Corrective Action Letter BR-03817_OUS dated May 2017 regarding “N Antiserum to Human Ceruloplasmin - Negative bias with N Protein Standard SL and N/T Protein Controls SL”.

Please read each question and indicate the appropriate answer.

Fax this completed form to Siemens Healthineers at the fax number provided at the bottom of this page.

1. I have read and understood the Urgent Field Corrective Action BR-03817_OUS 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 (###) ###-####. If you have any questions, contact your local Siemens technical support representative.