SIEMENS

Urgent Field Corrective Action

BR-05117

July 2017

N Antiserum to Human Ig/L-chain, λ-type
- Negative bias with lot 122204 using the urine application

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)	Lot Number	Expiration date
N Antiserum to Human Ig/L-chain, λ-type (urine application)	OWHH09	10446596	122204, 122204A, 122204C	2020-03-26

Reason for Correction

Siemens Healthcare Diagnostics has confirmed a negative bias of approximately -26% for results obtained with N Antiserum to Human Ig/L-chain, λ-type, using the urine application. In most but not all cases the issue is detected by QC testing using the LC1 and LC2 controls.

Note: The serum application for N Antiserum to Human Ig/L-chain, λ-type, works as intended.

Risk to Health

Under rare circumstances urine patient samples can be found incorrectly 26% lower than the true value. The overall risk to health is negligible as urine light chain testing exhibits a lagging phase of up to 8-10 months compared to serum before the test result turns positive (pathological status for Multiple Myeloma diagnosis) and shows some variance in relation to kidney function. Therefore, the serum application is the method of choice in the diagnosis for Multiple Myeloma as well as for therapy response and results of the test should always be interpreted in conjunction with the patient's history, clinical presentations and other findings.

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

Actions to be Taken by the Customer

Please discontinue use of the reagent lots listed in Table 1 for the urine application on light chain lambda testing.

The affected lots can still be used for the serum application for light chain lambda.

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 Ig/L-chain, λ-type determination using the product 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,

[redacted]

[redacted]

FIELD CORRECTION EFFECTIVENESS CHECK

N Antiserum to Human Ig/L-chain, λ-type
-Negative bias with lot 122204 using the urine application

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Corrective Action Letter BR-05117_OUS dated July 2017 regarding "N Antiserum to Human Ig/L-chain, λ-type - Negative bias with lot 122204 using the urine application". 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 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 Antiserum to Human Ig/L-chain, λ-type (urine application) OWHH09; SMN 10446596 Lot 122204, 122204A, 122204C		

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 the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.

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