SIEMENS Healthineers

Urgent Field Safety Notice

PP-22-003-A-C OUS

August 2022

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

N Antiserum to Human IgG – reduced antigen excess observed

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

Table 1. N Antiserum to Human IgG Affected Product(s), 2mL Variant

Reagent	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number	Expiration Date
N Antiserum to Human IgG, 2 mL Variant	10446296	0405686900179VF	153080M	2022-08-20
			153082K	2022-11-11
			153084	2023-02-10
			153086	2023-03-28
			153087	2023-05-17
			153089	2023-07-12
			153092	2023-09-15
			153095	2023-11-30
			153002A	2024-04-06
			153004	2024-06-27

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Table 2. N Antiserum to Human IgG Affected Product(s), 5 mL Variant

Reagent	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number	Expiration Date
N Antiserum to Human IgG, 5mL Variant	10446298	04056869001 79VF	153080N	2022-08-20
			153081E	2022-09-29
			153082L	2022-11-11
			153083	2022-12-07
			153084A	2023-02-10
			153085A	2023-02-22
			153086A	2023-03-28
			153087B	2023-05-17
			153088A	2023-06-14
			153089A	2023-07-12
			153090A	2023-08-17
			153092A	2023-09-15
			153093	2023-10-19
			153094	2023-11-29
			153097	2024-01-19
			153098	2024-02-14
			193099	2024-02-23
			153002	2024-04-06
			153003	2024-06-12

Please note: Future lots may be impacted by the issue but will then be provided with a corresponding pink note within the reagent package.

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Reason for Correction

The purpose of this communication is to inform you of an issue with the products indicated in Tables 1 and 2 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Products GmbH has confirmed that the N Antiserum to Human IgG lots listed in Tables 1 and 2 are not meeting the current High-Dose Hook Effect expectation given in the Instructions for Use (IFU) for the urine and CSF sample material. The N Antiserum to Human IgG IFU states that the reagent shows no high-dose hook effect in the IgGU assay up to 648 mg/L (urine) and IgGC assay up to 2290 mg/L (CSF).

The High-Dose Hook Effect expectation for the serum sample material (83.3 g/L) remains unchanged and is therefore not impacted by this field action.

For further information for the single N Antiserum to Human IgG lots, please see section “Actions to be Taken by the Customer”.

Siemens is currently investigating the root cause of this issue to restore the product to the original design.

As a risk mitigation measure for upcoming lots, we implemented an additional antigen excess check during the production of the N Antiserum to Human IgG product. If the specifications of the IFU are not met during production, a corresponding pink note will be included in the affected lots.

Risk to Health

The issue does not impact diagnosis or treatment. Therefore, a negligible health risk is associated to this issue. No look back is required.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Discontinue use of N Antiserum to Human IgG lot 153095 for urine and CSF sample determination. However, the N Antiserum to Human IgG lot 153095 can still be used for serum sample determination.
- All other N Antiserum to Human IgG lots listed in Tables 1 and 2 can be continued to be used with the following new preliminary high dose hook thresholds for urine and CSF:
    - Urine: 395 mg/L
    - CSF: 412 mg/L

  Further information regarding establishment of the preliminary high dose hook threshold can be found within section “Additional Information”.
- The specified high dose hook threshold within the IFU for serum (83.3 g/L) remains unchanged for all N Antiserum to Human IgG lots.

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- According to the IFU, in case of questionable results, the determinations should be repeated using the next higher sample dilution. For patient monitoring, consecutive immunoglobulin determinations should be performed from the same sample dilution, as far as possible.
- Review your inventory of the N Antiserum to Human IgG lot 153095 to determine your laboratory's replacement needs, if required, and to provide information to Siemens Healthineers for reporting to the authorities.
- If you have received any complaints of illness or adverse events associated with the products listed in Tables 1 and 2, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

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.

Additional Information

The high dose hook for urine and CSF have been assessed for all lots currently available on the market. The new preliminary thresholds for urine and CSF have been set conservatively based on the lowest thresholds observed at which no false negative (false normal) result was generated (see Figures 1 and 2 as example). The new preliminary thresholds are set as follows:

- Urine: 395 mg/L
- CSF: 412 mg/L

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N Antiserum to Human IgG – reduced antigen excess observed

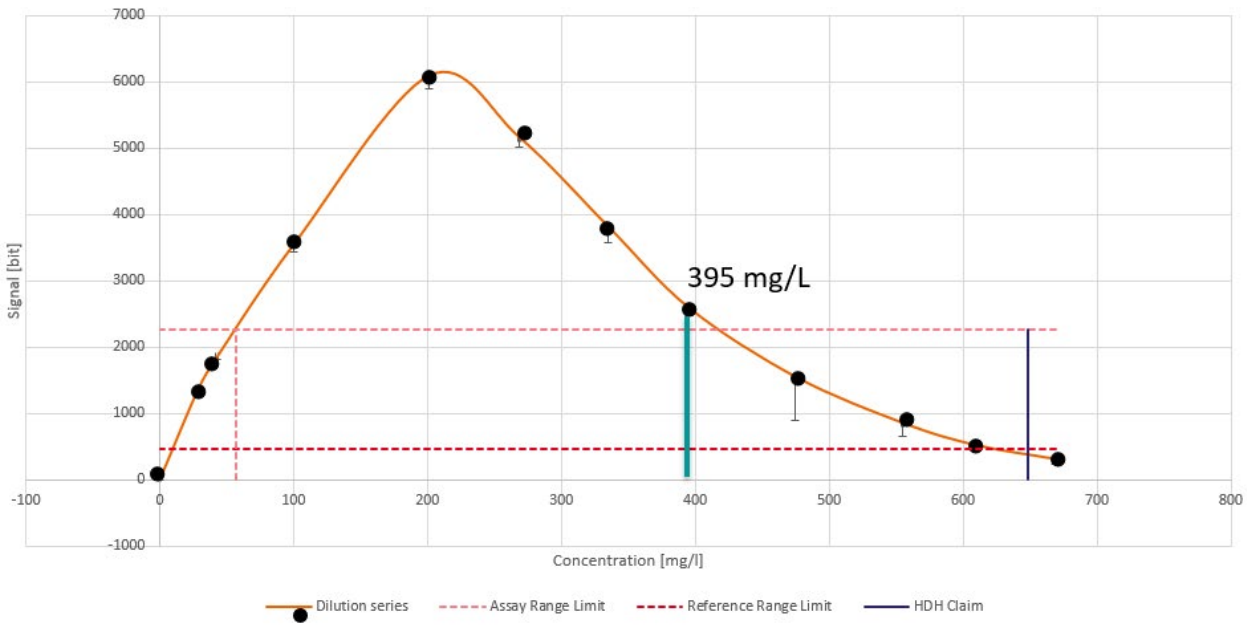

Figure 1 IgGU (urine) – N Antiserum to Human IgG lot 153002 (Limit: 395 mg/L)

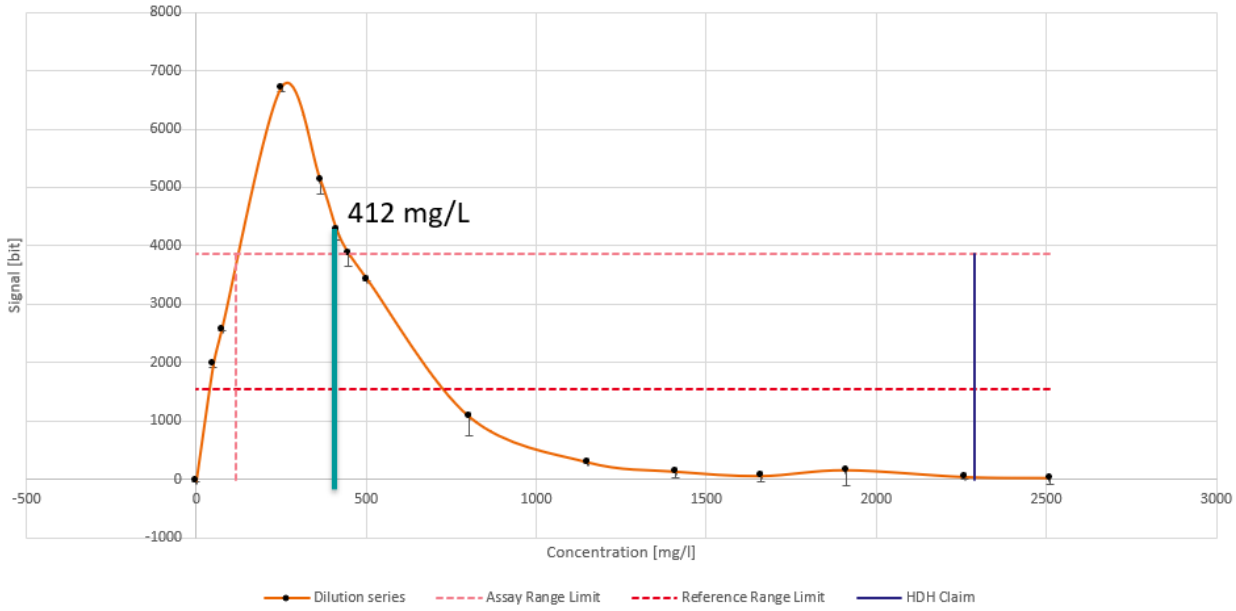

Figure 2 IgGC (CSF) – N Antiserum to Human IgG lot 153002 (Limit: 412 mg/L)

As stated, the data shown in Figures 1 and 2 are examples. Nevertheless, all other investigated N Antiserum to Human IgG lots listed in Table 1 and 2 (besides lot 153095) show similar behavior.

Sincerely yours,

This letter was created electronically and is valid without signature

i. V. Dr. Wolfgang Klein
Senior Manager
Quality Systems & Compliance

i. A. Dr. Lenard Mueller
Senior Marketing Manager
Global Marketing

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FIELD CORRECTION EFFECTIVENESS CHECK

N Antiserum to Human IgG – reduced antigen excess observed

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice PP-22-003-A-C OUS dated August 2022 regarding N Antiserum to Human IgG – reduced antigen excess 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 Field Safety Notice 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 Antiserum to Human IgG, SMN 10446296, Lot 153095	

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.

Or to fax this completed form to the Customer Care Center at XXXXXX.

If you have any questions, contact your local Siemens Healthineers technical support representative.

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