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Urgent Field Safety Notice:

**BNTM II System
 BN ProSpec® System / Atellica® NEPH 630 System**

N Antiserum to Human IgG – reduced antigen excess observed

To whom it may concern,

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 |

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 | 0405686900179VF | 153080N | 2022-08-20 |
| | | | 153081E | 2022-09-29 |
| | | | 153082L | 2022-11-11 |
| | | | 153083A | 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 |
| | | | 153099 | 2024-02-23 |
| | | | 153002 | 2024-04-06 |
| 153003 | 2024-06-12 | | | |
| 153004A | 2024-06-27 | | | |

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

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.
- 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

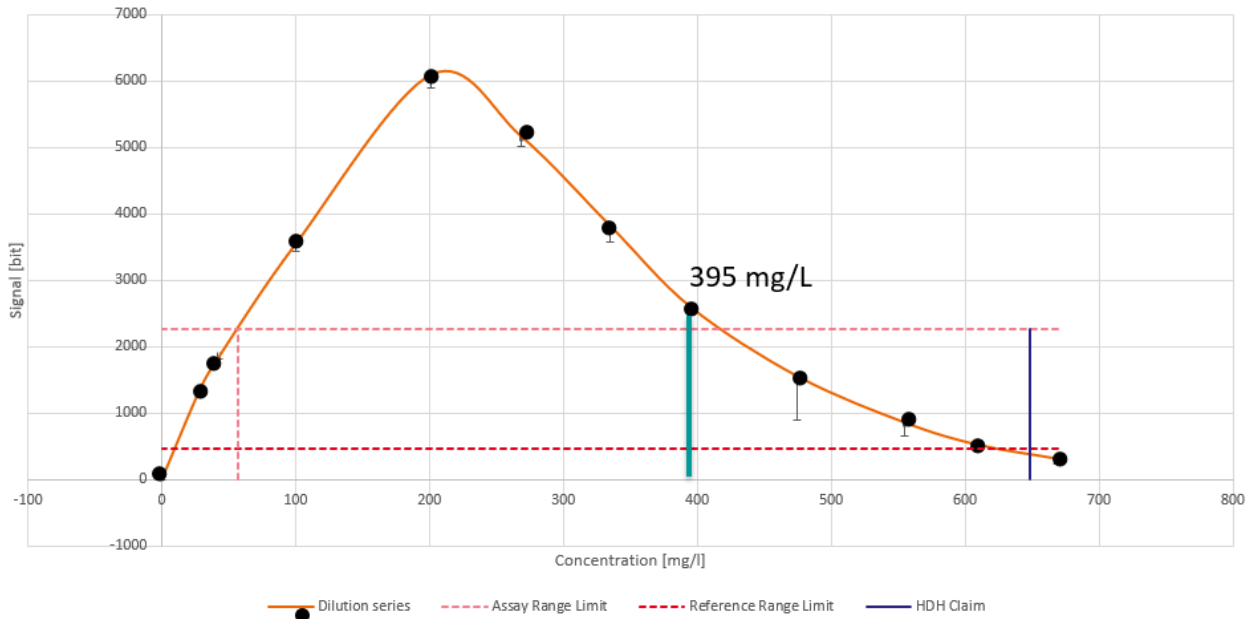


Figure 1 IgGU (urine) – N Antiserum to Human IgG lot 153002 (Limit: 395 mg/L)

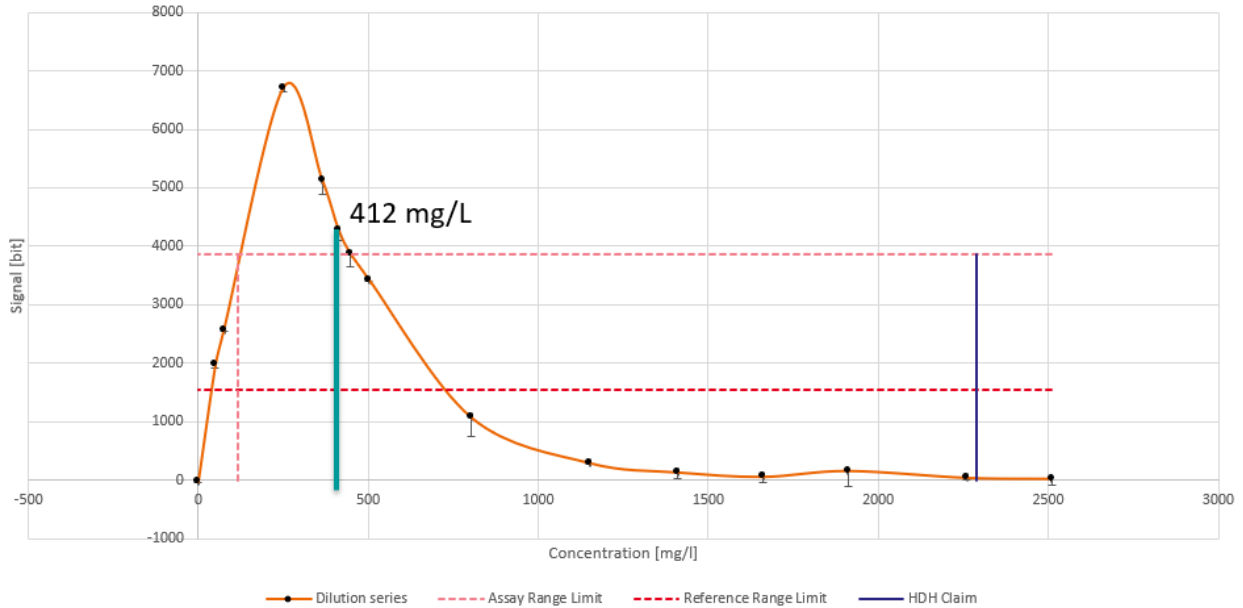


Figure 2 IgG (CSF) – N Antiserum to Human IgG lot 153002 (Limit: 412 mg/L)

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,

Siemens Healthcare Diagnostics GmbH

Electronically signed by: Gudrun Kapl
Reason: I am approving this document
Date: Sep 1, 2022 16:23 GMT+2

i.A. Dipl.-Ing. Gudrun Kapl

Electronically signed by: Otmar Baumgartner
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