

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

**N Antiserum to Human IgA and N Antiserum to Human IgM
– Incorrect high-dose hook effect claims for the sensitive applications**

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

Table 1. N Antiserum to Human IgA and N Antiserum to Human IgM

Affected Product(s)

Assay	Siemens Material Number (SMN)	Packaging Size	Unique Device Identification (UDI)	Lot Number
N Antiserum to Human IgA	10446292 10446294	1 x 2 mL 1 x 5 mL	0405686900178VD	All lots in shelf-life and future lots until further notice
N Antiserum to Human IgM	10446300 10446302	1 x 2 mL 1 x 5 mL	0405686900180UY	

Reason for Customer Notification

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

Siemens Healthcare Diagnostics Products GmbH has confirmed that the Instruction for Use (IFU) for N Antiserum to Human IgA and for N Antiserum to Human IgM might be misleading concerning that the reagents show no high-dose hook effect up to 58.6 g/L and 44.6 g/L respectively for the sensitive applications (IgAs, SAN 22 and IgMs, SAN 23).

We currently established new preliminary high-dose hook thresholds for the sensitive applications, which will soon be available in a revised IFU version for both assays. For more information, please refer to section “Actions to be Taken by the Customer”.

The high-dose hook effect claims for the standard applications of IgA (SAN 2) and IgM (SAN 3) are not impacted by this field action.

N Antiserum to Human IgA and Antiserum to Human IgM
- Incorrect high-dose hook effect claims for the sensitive applications

Actions to be Taken by the Customer

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- All lots in shelf-life and future lots of N Antiserum to Human IgA and the N Antiserum to Human IgM can be continued to be used with the following new preliminary high-dose hook thresholds for the sensitive applications:
 - IgAs: 10.4 g/L
 - IgMs: 4.48 g/L
- The specified high dose hook thresholds given in the IFUs for the standard applications of N Antiserum to Human IgA and IgM remain unchanged for all lots:
 - IgA: 58.6 g/L
 - IgM: 44.6 g/L
- According to both IFUs, 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.

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 at 1800-815-508 or your local Siemens Healthineers technical support representative.

Sincerely yours,

This letter was created electronically and is valid without signature.

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