

**BN ProSpec System and Atellica NEPH 630 System**

**Sporadically increased Albumin results compared to expected results**

Dear valued customer,

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

**Table 1. Affected BN ProSpec and Atellica NEPH 630 System(s)**

Instrument	Siemens Material Number (SMN)
BN ProSpec® System	10465217, 10462292, 10454727, 10444804, 10461865, 10461351, 10284475, 10463357
Atellica® NEPH 630 System	11239861

**Reason for Customer Notification**

Siemens has received complaints indicating very rare cases of increased Albumin results on the BN ProSpec System and Atellica NEPH 630 System.

Several contributing factors could be identified, i.e. a specific laboratory set-up (a certain combination of other tests in use, measurement scenario, throughput) combined with N Cuvette Segments (SMN 10446539) produced from a certain mold. These factors have to coincide in order to create the observed issue.

This customer notification will be provided to all BN ProSpec and Atellica NEPH 630 customers although most of them will not be affected by sporadically increased Albumin results.

We have identified measures for cuvette mold optimization that eliminate the issue. This optimization has already been implemented into the cuvette manufacturing process. Beginning with N Cuvette Segments produced in March 2019 (first lot 190790049), optimized cuvettes are available and in distribution.

**Risk to Health**

The overall risk to health is assessed with a negligible health risk as Albumin results are not used in isolation and clinically evaluated in the context of additional results and patient presentation. This takes into consideration all relevant different clinical indications or intended purposes of Albumin in serum, urine and CSF.

On basis of this assessment there is no look-back procedure recommended.

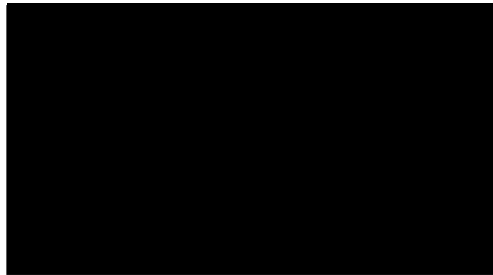
## **Actions to be Taken by the Customer**

Please review this letter with your Medical Director.

In case you experience sporadically increased Albumin results compared to expected results, contact your Siemens Customer Care Center for further follow-up.

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.



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