**BN II System**

**BN ProSpec System**

**Atellica NEPH 630 System**

siemens-healthineers.tld/keyword

**Customer Notification**

**PPC25-01.A.OUS**



|  |  |  |
| --- | --- | --- |
| **Title**  |  | N Latex RF Kit -white precipitates in some vials of N RF Reagent |
| **Date Issued** |  | December 2024 |
| **Issue Description** |  | Siemens Healthineers has confirmed through customer complaint and internal investigation that white precipitates were detected in some vials of N RF Reagent lot 110843. Using these affected vials on BN II, BN ProSpec® or Atellica® NEPH 630 Systems, the calibration, quality controls and or patient results will be flagged with a technical flag. If flagged, patient sample measurements should not be performed.If you observe white precipitates, please use a new vial of kit component N RF Reagent (homogenous white fluid without precipitates) before investigating other potential causes. If no flag appears, the reagent can be used as normal and patient sample measurements can be performed.Unfortunately, we currently cannot exclude that future lots might also be affected by the issue. We are working on the root cause identification to prevent that future lots suffer from the same issue. |
|  |  |  |
| **Products** |  | **Assay** | **Siemens Material Number/Unique Device Identification** | **Kit Lot Number** | **Manufacturing Date** | **Expiration Date** |
|  |  | N Latex RF Kit | 10445991/ 00842768006883 | 02812 (containing the affected N RF Reagent lot 110843)  | 27-Mar-2024 | 26-Mar-2025 |
|  |  | 10445992/ 00842768006890 | 02813 (containing the affected N RF Reagent lot 110843) |
|  |  |  |  |  |  |
|  |  |  |
| **Customer Actions** |  | * Until further notice please perform the following steps for the product(s) listed as well as future lot(s):

If you observe white precipitates, please use a new vial of kit component N RF Reagent (homogenous white fluid without precipitates). If no flag appears, the reagent can be used as normal and patient sample measurements can be performed. * If you observe white precipitates, you may request no-charge replacement product from your local Siemens Healthineers or distributor office. Please review your inventory of these products and assess your laboratory’s replacement needs. Please note that there may be delivery delays due to the current situation.
* Complete and return the Product Replacement Form attached to this letter.
* Please retain this letter with your laboratory records and forward this letter to those who may have received the product.
 |
|  |  |  |
| **Single Registration Number (SRN)** |  | DE-MF-00005039 |
|  |  | 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.Sincerely yours,This letter was created electronically and is valid without signature.i.V. Nils Neumann i.A. Dr. Christian MirwaldtDirector Marketing ManagerQuality Systems & Compliance Global Marketing |

Atellica and BN ProSpec are registered trademarks of Siemens Healthcare Diagnostics Marburg Products GmbH.

 **PRODUCT REPLACEMENT FORM**

This response form is to request no charge replacement product for the enclosed Siemens Healthineers Customer Notification **PPC25-01.A.OUS** dated Dec. 2024. Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1 immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Return this completed form as per the instructions provided at the bottom of this page.

|  |  |  |
| --- | --- | --- |
| 1. Do you have the affected product(s) on hand? Please check inventories before answering.
 | Yes [ ]  | No [ ]  |
| 1. Were affected Site Personnel notified?
 | Yes [ ]  | No [ ]  |
| 1. Was a copy of the letter retained and posted with the current product labeling?
 | Yes [ ]  | No [ ]  |

If the answer to the question #1 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** |
| *(Insert information from Table in Page 1)* |  |
|  |  |
| **Name of person completing questionnaire:** |  |
| **Title:** |  |
| **Institution:** |  |
| **Street:** |
| **City:** |  | **State:** | **Zip Code:** |
| **Phone:** |  | **Country:** |  |

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**

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.