Urgent Field Safety Notice

CC 20-01.A-2.OUS

December 2019

Atellica® Solution

Atellica IM NT-proBNP (PBNP) Positive Bias to Predicate Method

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

Table 1. Atellica® IM Affected Product(s)

Assay	Siemens Material Number (SMN)	Lot Number
Atellica IM NT-proBNP (PBNP) 100 Test Kit	11200588	All Lots ending in 022 and above
Atellica IM NT-proBNP (PBNP) 500 Test Kit	11200589	

Reason for Urgent Field Safety Notice

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

Siemens Healthcare Diagnostics Inc. confirmed an average method comparison regression bias of up to 13% with Atellica IM NT-proBNP (PBNP) Assay kit lots listed in Table 1 when compared to the predicate method in the Instructions for Use (IFU). See Additional Information section below for details of the observed bias.

Siemens' investigation verified that the Atellica IM PBNP assay continues to meet the reference intervals listed in the Atellica IM PBNP Instructions for Use (IFU) and concordance (agreement) to the predicate method is greater than or equal to 95% as shown in Table 2 below.

Table 2. Atellica IM PBNP Concordance to Predicate Method

Atellica IM	
Reference Interval	Percent Concordance
125 pg/mL	98%
450 pg/mL	95%

Siemens is currently investigating root cause of the method comparison bias observed and will send a follow up communication when further information is available.

Risk to Health

The potential exists to confound the differential diagnosis between heart failure and pulmonary cause of dyspnea. NT-proBNP results would be correlated to clinical history and presentation as well as to other testing such as results of chest radiograph, ejection fraction and/or echocardiography, and other laboratory evaluations.

Siemens is not recommending a review of previously generated results.

511 Benedict Ave
Tarrytown, NY 10591

Actions to be Taken by the Customer

- You may continue to use Atellica IM PBNP Lots as described in Table 1; concordance to predicate has been demonstrated and the reference intervals were verified.
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

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

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.

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Additional Information

Method comparison studies included n=124 samples across the assay measuring interval (35 - 35,000 pg/mL; 4.13 - 4130 pmol/L) comparing Atellica IM PBNP versus the predicate method utilizing Passing Bablok regression analysis.

Figure 1 and 2 below display the highest biased method comparison data observed with Atellica IM PBNP versus the predicate method.

Figure 1. Atellica IM PBNP Method Comparison to Predicate Method Graph

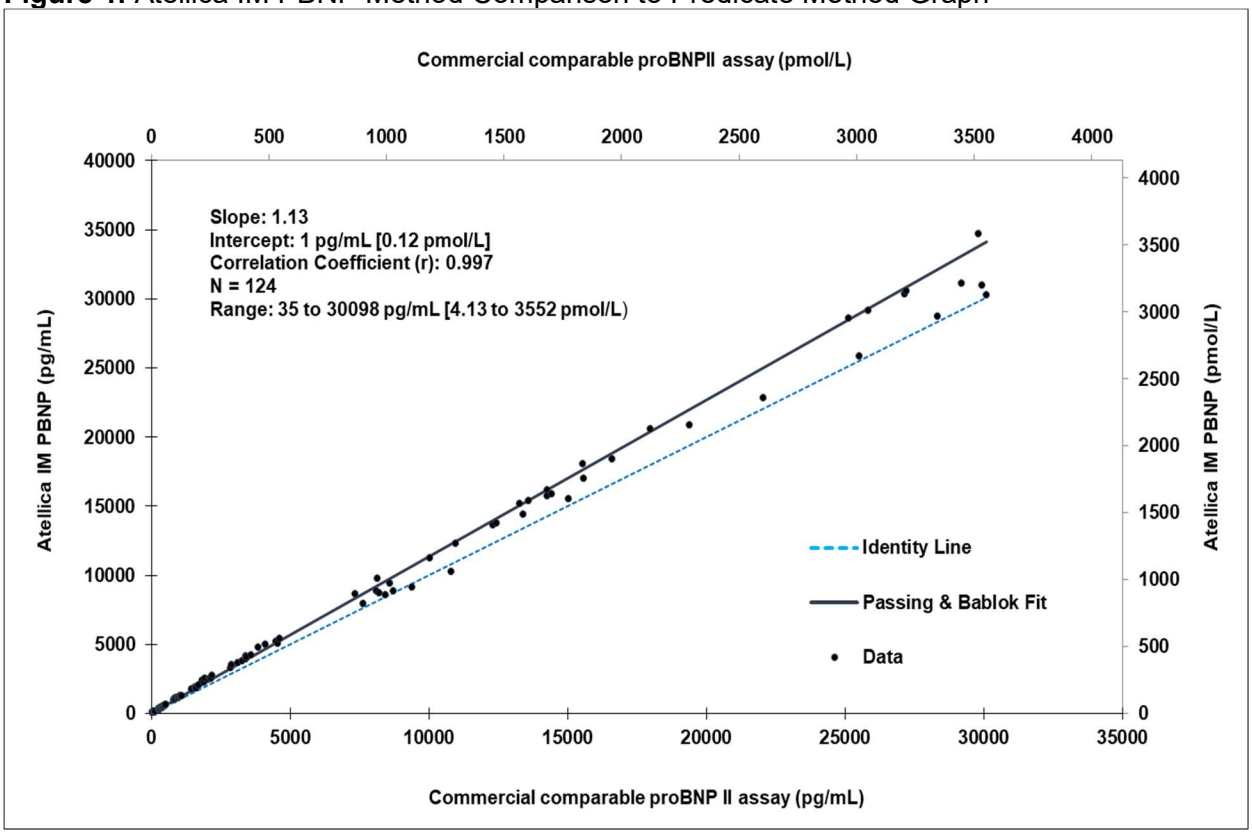


Figure 2. Atellica IM PBNP Method Comparison to Predicate Method % Difference Plot

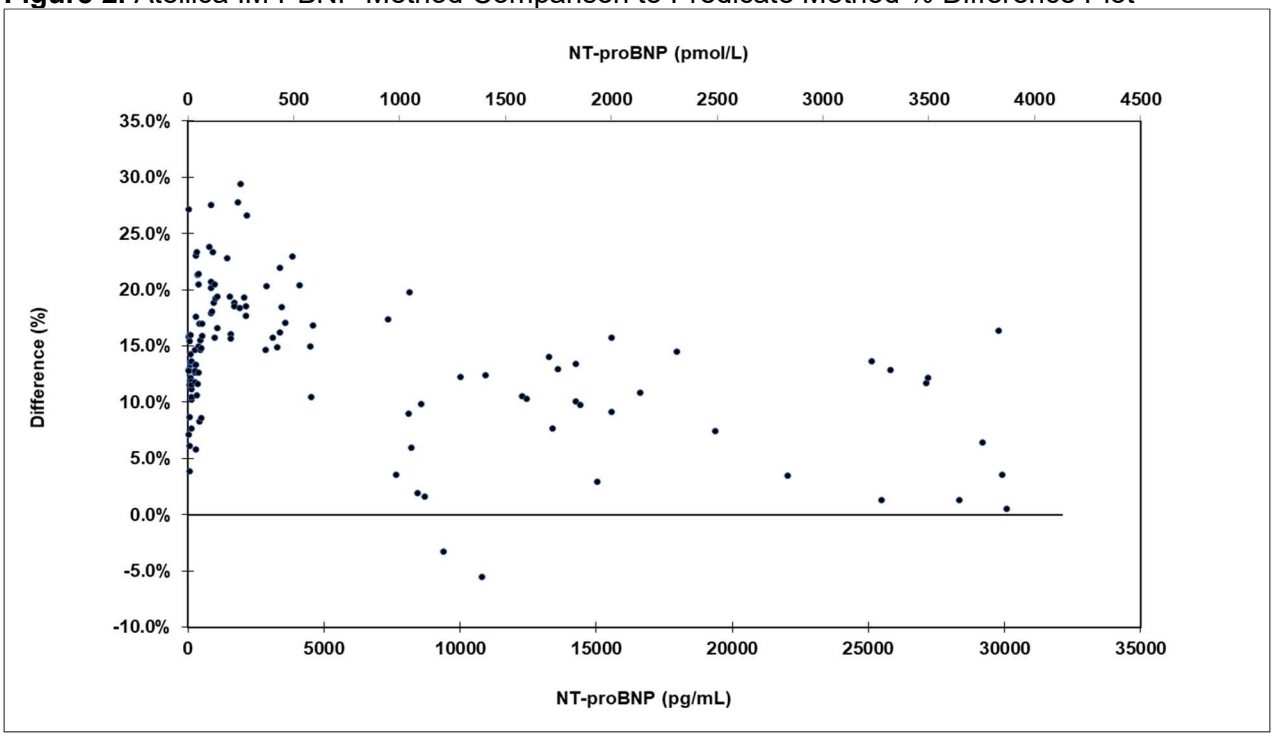
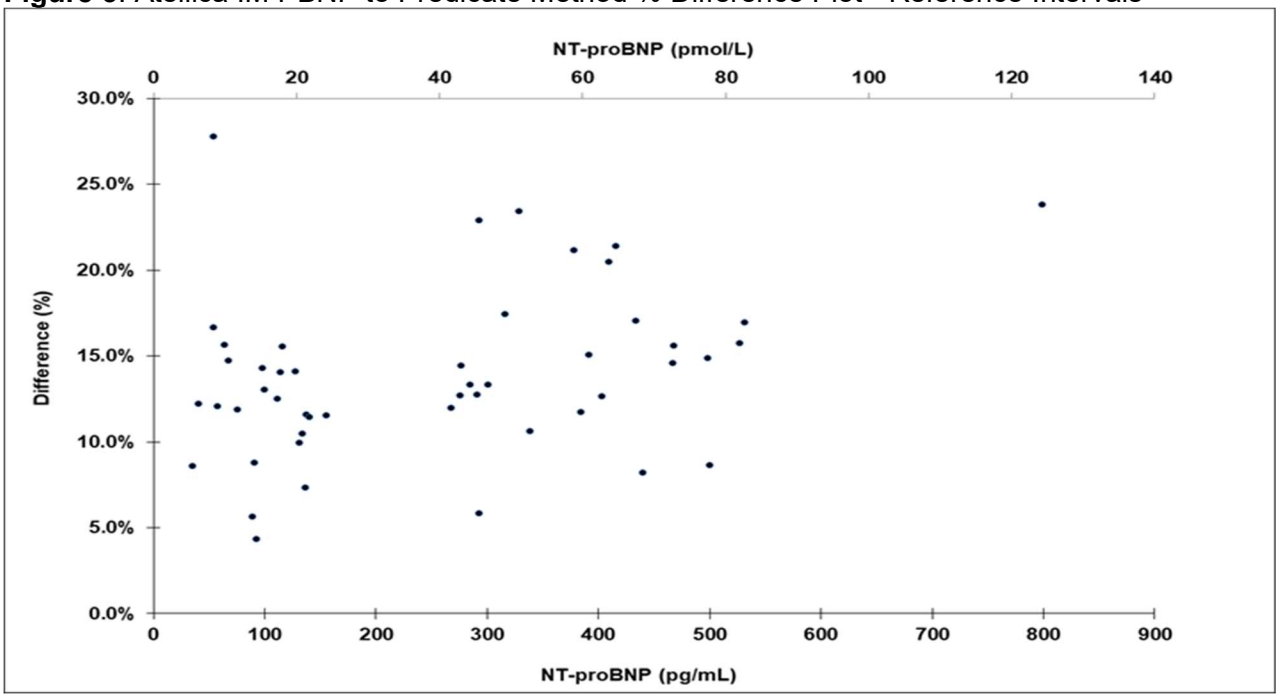


Figure 3 is a subset of the % differences from Figure 2, highlighting the reference interval cut-offs of 125 pg/mL (15.7 pmol/L) and 450 pg/mL (53.1 pmol/L).

Figure 3. Atellica IM PBNP to Predicate Method % Difference Plot - Reference Intervals



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FIELD CORRECTION EFFECTIVENESS CHECK

Atellica IM NT-proBNP (PBNP) Positive Bias to Predicate Method

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CC 20-01.A-2.OUS dated December 2019 regarding Atellica IM NT-proBNP (PBNP) Positive Bias to Predicate Method. Please read the 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 ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

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

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

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