SIEMENS

Urgent Field Safety Notice

PH-18-004-OUS

March 2018

Atellica COAG 360 -
Potential for erroneous results at the LIS when result factors have been customized by using Assay Customization or LIS Connection

Dear valued customer,

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

Table 1. Affected Product(s)

Assay	Siemens Material Number (SMN)
Atellica COAG 360 System	10707173, 10759658

Reason for Customer Notification

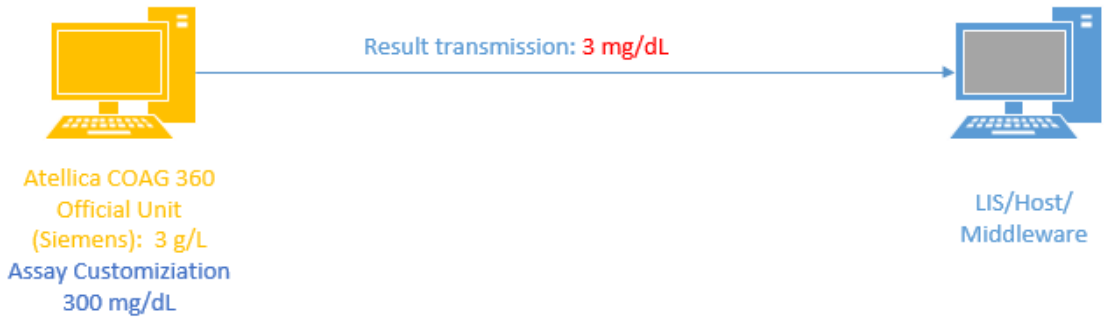
Siemens has confirmed that a conversion of a result unit can lead to an erroneous result transmitted to the LIS.

If you are not using any customization or conversion factors, you will not be affected.

The issue may occur under two different scenarios:

1. Atellica COAG 360 Menue – Setup - Assay Customization:

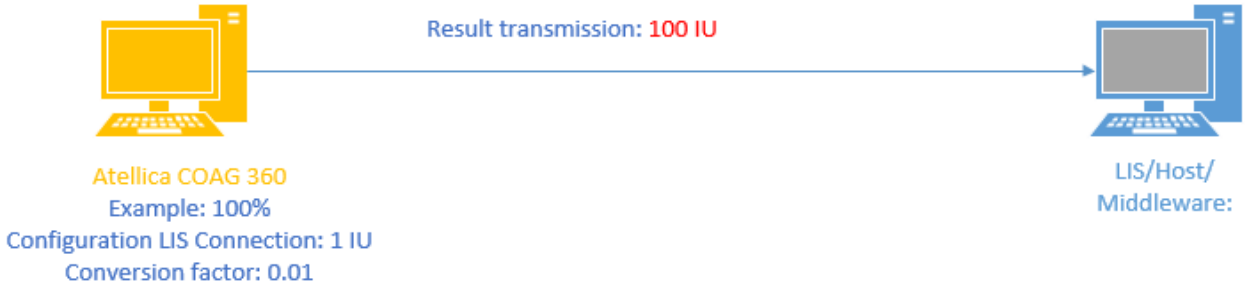
By the Assay Customization, visualization of results can be adapted by conversion into another unit. The software utilizes a conversion factor for calculation of the result values (e.g. assay conversion for fibrinogen from g/L to mg/dL with a conversion factor 100). The results displayed in the Atellica COAG 360 job list change to the selected unit with the recalculated result values due to the Assay Customization (e.g. 300 mg/dL fibrinogen instead of 3 g/L) whereas the values sent to the LIS are the original result values but with the customized result unit (3 mg/dL). This can lead to discrepant results reported via LIS:



Example: Assay conversion for Fibrinogen from g/L into mg/dL.

2. Atellica COAG 360 Menue – Setup -LIS Connection/Configuration/Assay Data:

The configuration of the LIS Connection allows the definition about how results are displayed in the LIS. There is the possibility to adapt the unit with a corresponding factor. If the factor is given with decimals, this value will be rounded to the next integer unit upon transfer to LIS, although it is visually stored correctly. This can lead to discrepant results reported via LIS:



Overall Risk to Health

There is a potential risk to health associated with the analytes D-dimer (INNOVANCE D-Dimer) and/or Fibrinogen when impacted by these issues. Discordant results due to incorrect unit transmission or by erroneous factor conversion may affect the decision making based on common guidances.
As the probability of occurrence is extremely low, the overall risk to health for both issues is low.

Actions to be Taken by the Customer

1. When using the Assay Customization, please verify that the transmitted results are correct.

2. For the LIS Connection, no numbers with decimals shall be used. Please use only integer factors (e. g. 10, 100 etc.) or the units officially released from Siemens.

An updated software version with the solution for this issue is currently expected for May 2018.

Please Complete and return the Urgent Field Corrective Action 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 Customer Care Center or your local Siemens technical support representative.

Sincerely yours,

Dr. Norbert Dedner
Senior Director
Quality Systems & Compliance

Andreas Bermann
Senior Director
Global Marketing Hemostasis

FIELD CORRECTION EFFECTIVENESS CHECK

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This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice letter PH-18-004_A_OUS dated March 2018 regarding “Atellica COAG 360 - Potential for erroneous results at the LIS when result factors have been customized by using Assay Customization or LIS Connection”. Please read each question and indicate the appropriate answer.

Fax this completed form to Siemens Healthineers at the fax number provided at the bottom of this page.

1. I have read and understood the Urgent Field Corrective Action instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Customer Sold To #: Customer Ship To #:

Please fax this completed form to the Customer Care Center at (312) 275-7795. If you have any questions, contact your local Siemens technical support representative.