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**Urgent Field Safety Notice:**

**Atellica® COAG 360 System Software Version 1.8**

**Automatic re-dilutions not measured**

Dear Sirs,

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

**Table 1. Atellica COAG 360 Systems Affected Product(s)**

| Atellica COAG 360 System Software Version | Siemens Material Number (SMN) |
|---|---|
| 1.8 | 11468626 |

## Reason for Correction

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 must take.

Siemens Healthcare Diagnostics Products GmbH has confirmed that the Atellica COAG 360 Software Version 1.8 may cause a delay in patient sample result reporting as the automatic re-dilutions are not measured under certain conditions:

- A sample result fulfills the criterion for a required automatic re-dilution
- Request for the automatic re-dilution is set and no further measurement is placed in the Joblist or in the Control Journal

Siemens Healthcare Diagnostics Products GmbH investigated the issue and determined as root cause a software bug and the solution will be provided with the upcoming Atellica COAG 360 System Software Version 1.9.

Please see section Additional Information, which provides a workaround to avoid not performed automatic re-dilutions.

## Risk to Health

A low health risk is associated to this issue as due to the lack of information the above described issue may lead to a delay in reporting of patient sample results for emergency / urgency samples.

As no results were obtained in the failure mode, it is not necessary to review previous test results or to repeat testing. Therefore, also no look back is required.

## Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Perform the instructions provided in Additional Information.
- Complete and return the Field Correction Effectiveness 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.

## Additional Information

Following procedure describes the workaround to avoid not performed automatic re-dilutions (see Table 2, which lists the methods which may initiate an automatic re-dilution if required and are therefore influenced by the issue).

- If the automatic re-dilution is the last measurement order, this re-dilution will not be started.
- Select any other measurement request in the Joblist / Control Journal or place a new sample / control vial (with open orders) in the Sample Manager.
- As soon as the Atellica COAG 360 System starts to plan this ordered measurement, the open re-dilution testing will be performed as well, and a corresponding finalization time will be displayed.
- To save sample material and reagent, the additional request that was used to trigger to start the measurement of the automatic re-dilution measurement may be deleted afterwards, if this was not required.
- Please Note: A deletion of the remaining automatic re-dilution request is not recommended, as the initial testing will be repeated, and the issue of the delayed automatic re-dilution might happen again.

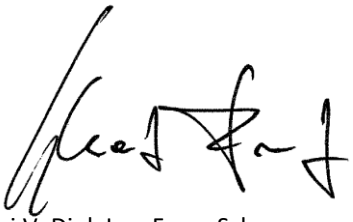
**Table 2. Atellica COAG 360 Systems Affected Method(s)**

| Assay Name | Assay No. | Condition for re-Dilution | Alternative Dilution | |
|---|---|---|---|---|
| Antithrombin Ag | 14200 | If result is below calibration range use dilution | 1: | 2 |
| | | If result is above calibration range use dilution | 1: | 8 |
| Antithrombin Berichrom (Anti IIa) | 14000 | If result is above calibration range use dilution | 1: | 12 |
| C1-Inhibitor Berichrom | 33100 | If result is below calibration range use dilution | 1: | 2 |
| | | If result is above calibration range use dilution | 1: | 8 |
| D-Dimer INNOVANCE mg/L FEU | 15000 | If result is above calibration range use dilution | 1: | 10 |
| D-Dimer INNOVANCE µg/L FEU | 15010 | If result is above calibration range use dilution | 1: | 10 |
| D-Dimer LOCI µg/L FEU | 71000 | If result is above 9000 µg/L FEU use dilution | 1: | 3 |
| D-Dimer LOCI mg/L FEU | 71001 | If result is above 9 mg/L FEU use dilution | 1: | 3 |
| Factor IX Actin FS | 27100 | If result is above calibration range use dilution | 1: | 16 |
| Factor IX Actin FS 1:2 | 27101 | If result is above calibration range use dilution | 1: | 16 |
| Factor IX Actin FS 1:4 | 27102 | If result is above calibration range use dilution | 1: | 16 |
| Factor IX Actin FSL | 27200 | If result is above calibration range use dilution | 1: | 40 |
| Factor IX Pathromtin SL | 27000 | If result is above calibration range use dilution | 1: | 40 |
| Factor VIII Actin FS | 26100 | If result is above calibration range use dilution | 1: | 16 |
| Factor VIII Actin FS 1:2 | 26100 | If result is above calibration range use dilution | 1: | 16 |
| Factor VIII Actin FS 1:4 | 26100 | If result is above calibration range use dilution | 1: | 16 |
| Factor VIII Actin FSL | 26200 | If result is above calibration range use dilution | 1: | 40 |
| Factor VIII Pathromtin SL | 2600 | If result is above calibration range use dilution | 1: | 40 |
| Factor XI Actin FS | 29100 | If result is above calibration range use dilution | 1: | 20 |
| Fibrinogen Multifibren U | 13100 | If result is above calibration range use dilution | 1: | 2 |
| Fibrinogen Thrombin Reagent | 13000 | If result is below 1,05 g/L use dilution | 1: | 1 |
| | | If result is above 4,8 g/L use dilution | 1: | 6 |
| FVIII chromogenic | 26400 | If result is above calibration range use dilution | 1: | 30 |
| Von WillebrandFactor (vWF Ac) | 16001 | If result is above 150 % use dilution | 1: | 12 |
| Von WillebrandFactor (vWF Ag) | 16000 | If result is above 170 % use dilution | 1: | 8 |

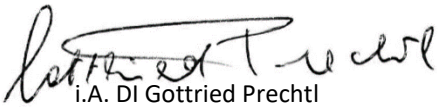
We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Remote Services Center of your local Siemens Healthineers Technical Support Representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH



i.V. Dipl. Ing. Franz Schwarz
Quality Management CEE



i.A. DI Gottried Prechtl
Product Manager Austria & SEE