# SIEMENS

## Atellica COAG 360
## Software bug affecting Derived Fibrinogen Results and PT% Calibration Curves

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 when importing lot data to the Atellica COAG 360 system, a software bug affects derived Fibrinogen results and the validation of the PT% calibration curves via provided check curves.

Derived Fibrinogen

Using lot data provided for derived Fibrinogen Master Curves for Thromborel® S (Assay No. 12000; Short Name: Fib der TS) or Dade® Innovin® (Assay No. 12100; Short Name: Fib der In) will lead to results above the reference range for all measured samples and controls.

Thromborel S Example:
For a raw value of 540 mA the result with a correct master curve is 2.0 g/L.
The result with the erroneous master curve is given as >3.5 g/L.
Reference range for Derived Fibrinogen with Thromborel S is 1.8 – 3.5 g/L.

Innovin Example:
For a raw value of 348 mA the result with a correct master curve is 2.4 g/L.
The result with the erroneous master curve is given as >3.7 g/L.
Reference range for derived Fibrinogen with Innovin is 1.9 – 3.7 g/L.

Reason for this issue is a bug in current Atellica COAG 360 software versions which causes that the raw values and the values of the concentrations are mixed up.

PT % calibration curve outside acceptance range

PT% calibration curves for Thromborel S (Assay No. 10010; Short Name: PT % TS) or Dade Innovin (Assay No. 10110; Short Name: PT % In) will always be flagged with "Calibration curve outside acceptance range" when a corresponding check curve is imported from the lot data download.

---

**Siemens Healthcare Diagnostics Products GmbH**.
All Rights Reserved.

Emil-von-Behring Straße 76
D – 35041 Marburg, Germany

Similar in regards to the effect for derived Fibrinogen, the reason for this issue is a bug in current Atellica COAG 360 software versions which causes that the raw values and the values of the concentrations only for the check curves are interchanged.

**Overall Risk to Health**

There is negligible health risk. The issue will lead to a 100 % flagging rate for a PT% calibration curve as well as non-reportable derived Fibrinogen results. The issue described above only affects the Atellica COAG 360 system and the impact is limited to Thromborel S and Innovin lots for which data are given on the Lot Data file.

**Actions to be Taken by the Customer**

Derived Fibrinogen:
In case you are using this parameter, the correct derived Fibrinogen master curve can be entered manually onto the Atellica COAG 360. Please follow instructions attached or contact your local Application Specialist.

PT % Calibration curve outside acceptance range:
Please check if the affected calibration curve appears correct. In case the curve is visually plausible, please activate this PT% calibration curve manually and validate the curve by using both a normal and a pathological control. In case all control values recover within the assigned ranges, the calibration curve can be used. Please follow instructions attached or contact your local Application Specialist.

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                                    Eva-Maria Landmann
Senior Director                                          Marketing Manager
Quality Systems & Compliance                  Global Marketing Hemostasis

Attachment:  Workaround for Urgent Field Corrective Action PH-18-002_OUS

Atellica, Thromborel, Dade & Innovin are a trademarks of Siemens Healthcare Diagnostics Inc or its affiliates.

**Siemens Healthcare Diagnostics Products GmbH**.
All Rights Reserved.

Page 2 of 3

Emil-von-Behring Straße 76
D – 35041 Marburg, Germany

Urgent Field Corrective Action  PH-18-002_OUS – March 2018

**FIELD CORRECTION EFFECTIVENESS CHECK**

Atellica COAG360

Software bug affecting Derived Fibrinogen Results and PT% Calibration Curves

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Corrective Action letter PH-18-002_OUS dated March 2018 regarding 'Atellica COAG360 - Software bug affecting Derived Fibrinogen Results and PT% Calibration Curves'. 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.

**Siemens Healthcare Diagnostics Products GmbH**.
All Rights Reserved.

Emil-von-Behring Straße 76
D – 35041 Marburg, Germany

Page 3 of 3

Urgent Field Corrective Action  PH-18-002_OUS – March 2018

# Workaround
# for

# Urgent Field Corrective Action
# PH-18-002-OUS

# on the
# Atellica COAG 360 System

## General Information

This information addresses the actions to be taken by the customer regarding the Urgent Field Corrective Action PH-18-002-OUS in regards to the software bug affecting the lot data import with impact on derived Fibrinogen and PT%. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

## Systems / Products Affected

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

## Affected Software Versions

Atellica COAG360 System software version 1.1.2 and below.

## Workaround – Derived Fibrinogen

Derived Fibrinogen Master curves appear automatically in the "Calibration" overview dialogue, written in blue letters.
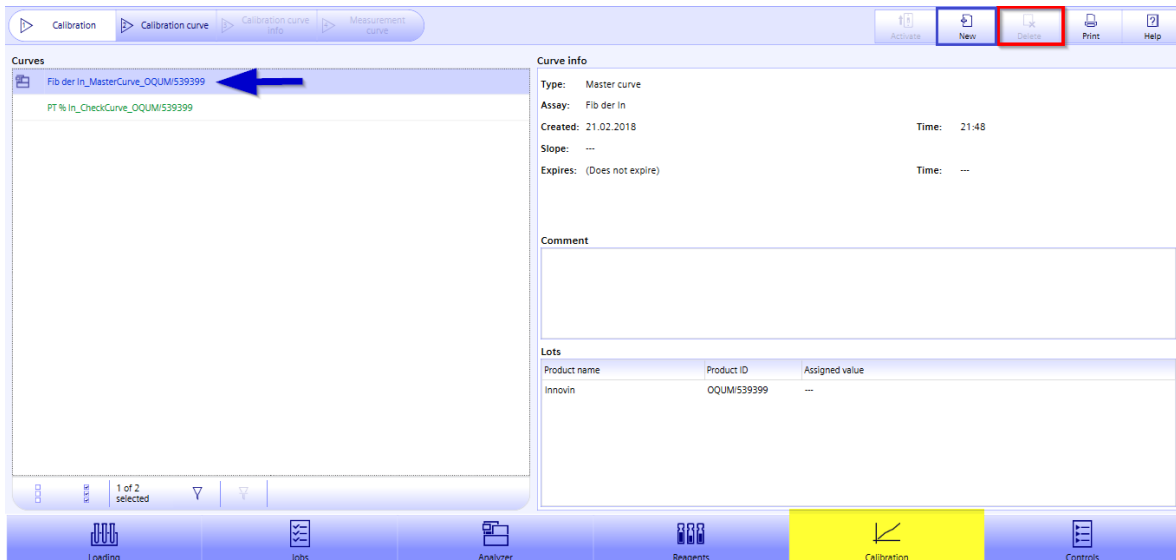


**Picture 1.1: Example Derived Fibrinogen Mastercurve of Innovin e. g. lot 539399**

Master curves are not changeable and cannot be deleted (see Picture 1.1; red square).

To enable the correct derived Fibrinogen calculation, a correct derived Fibrinogen calibration curve has to be entered manually.

Click on the button "New" (Picture 1.1; blue square) to enter the derived Fibrinogen calibration curve.



**Picture 1.2: Enter the derived Fibrinogen calibration curve manually (example Innovin lot 539399)**

1. Choose corresponding derived Fibrinogen assay
   - For Innovin - **Fib der In**
   - For Thromborel S - **Fib der TS**
2. Choose "Enter curve manually"
3. Select your PT reagent lot in use
4. Enter the correct derived Fibrinogen master curve values for the Atellica COAG360, which can be found in the TAV documents of the respective PT reagent lot.
5. Press "Save curve" button

**Picture 1.3: Active derived Fibrinogen calibration curve manually entered (example Innovin lot 539399)**

Please make sure that the manually entered calibration curve is marked with the analyzer symbol. This symbol indicates that the derived Fibrinogen curve is activated and will be used for derived Fibrinogen calculation. Please validate by QC measurement.
The original derived Fibrinogen master curve (written in blue letters) is now marked with a green tick, which indicates that this curve is currently not in use.

## Workaround – PT % calibration curve outside acceptance range

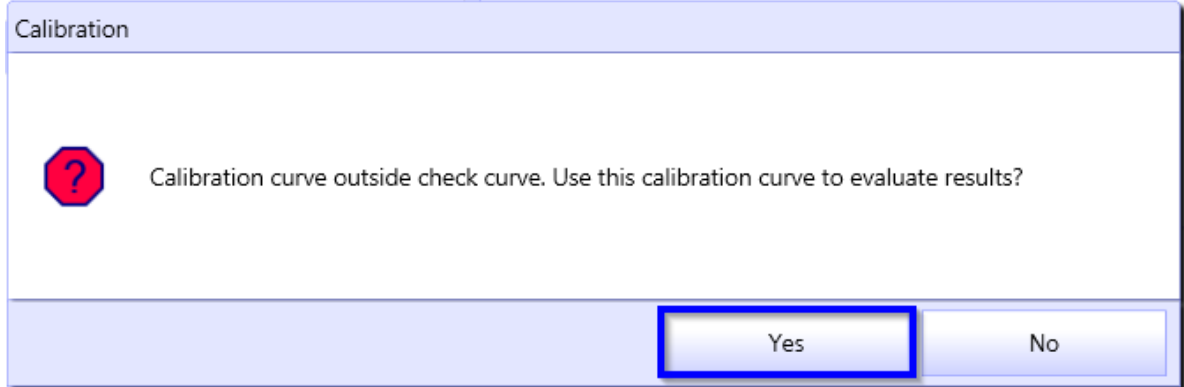PT% calibration curves for

- Thromborel S   Assay No. 10010        Short Name: PT % TS
- Dade Innovin   Assay No. 10110        Short Name: PT % In

will always be flagged with "Result invalid / Calibration curve outside acceptance range" (see Picture 2.1; red exclamation mark) when a corresponding check curve (see Picture 2.1; written in green letters) is available on the system. The check curves are not changeable and cannot be deleted.
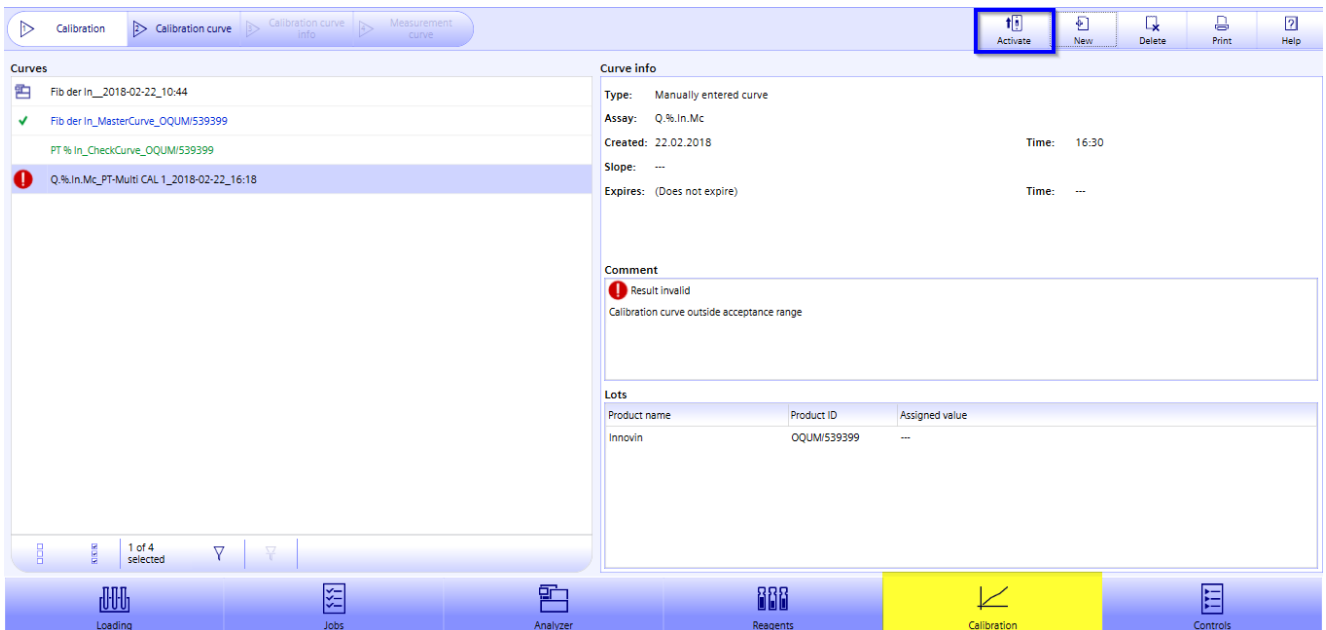


**Picture 2.1: PT % calibration curve outside acceptance range (example Innovin lot 539399)**

The measured PT% calibration curve should be checked visually and can afterwards be activated via the button "Activate".

**Picture 2.2: Confirmation screen after activation**

The system will ask for a confirmation, click on Yes.

The PT% calibration curve is now marked with the analyzer symbol. This symbol indicates that the curve is activated.

Please validate the curve by using both a normal and a pathological control!
In case all control values recover within the assigned ranges, the calibration curve can be used for further testing.