

Urgent Field Corrective Action

BR-07617-OUS

October 2017

Atellica COAG360

inappropriate range over reporting under certain reflex testing conditions using an alternative dilution

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

Reason for Urgent Field Corrective Action

Siemens has confirmed that under very rare conditions an inappropriate range over reporting for certain reflex testing conditions exists.

The issue occurs only if the following conditions meet:

- The assay is performed with an alternative dilution

AND

- The result exceeds the borders of the calibration range or the borders of the extrapolation range, if applicable.

In such a case the result reported is given inconsistently with the limits of the initial calibration range or extrapolation range without considering the dilution factor of the alternative dilution.

Actions to be Taken by the Customer

The issue is fixed with the new Software Patch 1.1.1. This is available for installation.

Please contact your local Siemens representative to receive SW Patch 1.1.1 to be installed on your Atellica COAG 360 system.

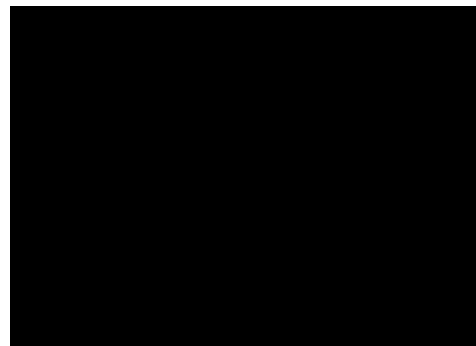
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Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

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,



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FIELD CORRECTION EFFECTIVENESS CHECK

Atellica COAG360

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This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Corrective Action letter BR-07617_OUS dated October 2017 regarding 'Atellica COAG360 - inappropriate range over reporting under certain reflex testing conditions using an alternative dilution'. 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 Customer Notification 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.