

Atellica® COAG 360 System
BCS® XP System
BFT II Analyzer
Sysmex® CA-500/CA-600 Series
Sysmex CA-1500 System
Sysmex CA-7000 System
Sysmex CS-2000i System
Sysmex CS-2100i System
Sysmex CS-2500 System
Sysmex CS-5100 System
Mechanical systems

Dade® Ci-Trol 1 – broader confidence interval for Fibrinogen using Dade Thrombin Reagent or Multifibren U are provided in the Table of Assigned Values

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

Table 1. Affected Product(s)

Atellica COAG 360 System, BCS XP System, BFT II Analyzer, Sysmex CA-500/CA-600 Series, Sysmex CA-1500 System, Sysmex CA-7000 System, Sysmex CS-2000i System, Sysmex CS-2100i System, Sysmex CS-2500 System, Sysmex CS-5100 System and Mechanical systems

| Product | Catalog Number | Siemens Material Number (SMN) | Kit Lot Number | Expiration Date (YYYY-MM-DD) | Manufacturing Date (YYYY-MM-DD) |
|----------------|-----------------------|--------------------------------------|-----------------------|-------------------------------------|--|
| Dade Ci-Trol 1 | 291070 | 10445601 | 564805 564805A | 2022-06-30 | 2019-07-01 |
| | | | 564810 564810A | 2022-10-13 | 2019-10-14 |

Reason for Correction

Siemens Healthcare Diagnostics has observed that assigned confidence intervals for Fibrinogen are broader than expected. This applies to the Table of Assigned Values (TAV) for Dade Ci-Trol 1 (refer to Dade Ci-Trol 1 lots given in Table 1) when using Dade Thrombin Reagent or Multifibren U.

Siemens Healthcare Diagnostics has corrected the confidence interval for Fibrinogen of the Dade Ci-Trol 1 lots listed in Table 1 for use with Dade Thrombin Reagent or Multifibren U. The Fibrinogen assigned values itself are not affected and remain the same.

Therefore, the affected Dade Ci-Trol 1 lots can be used but the revised confidence interval must be used.

Risk to Health

The issue has been assessed to commensurate with a negligible health risk as the assigned values provided in the TAV are correct. The anchoring is based on the assigned value provided and not primarily on the lower and upper limits of the confidence intervals. Furthermore, for important biomarkers as fibrinogen, the different guidelines stipulate tight(er) borders around the target value what might lead to increased failed QC results.

Actions to be Taken by the Customer

For further use of the affected Dade Ci-Trol 1 controls, please proceed as follows:

- Use the assigned values and revised respective confidence intervals of the Dade Ci-Trol 1 control provided in Table 2 for Fibrinogen using Dade Thrombin Reagent or Multifibren U.
- For Atellica COAG 360 System customers, a new Lot Data File is expected to be available by the mid of March including the revised Dade Ci-Trol 1 Fibrinogen confidence intervals for Dade Thrombin Reagent and Multifibren U.
- If you have received any complaints of illness or adverse events associated with the incorrectly assigned confidence intervals for Dade Thrombin Reagent or Multifibren U using the products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens technical support representative.
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

Table 2. Corrected Dade Ci-Trol 1 Confidence Intervals

| Affected Control | Affected Control Lot | Reagent | System | Assigned Value | Confidence Interval |
|------------------|----------------------|-----------------------|--------------------------|----------------|---------------------|
| Dade Ci-Trol 1 | 564805 564805A | Multifibren U | BFT II | 2.6 g/L | 2.3 – 2.9 g/L |
| | | | BCS XP | 2.7 g/L | 2.4 – 3.0 g/L |
| | | | Atellica COAG 360 System | 2.7 g/L | 2.4 – 3.0 g/L |
| | | Dade Thrombin Reagent | Sysmex CA/CS Systems | 2.67 g/L | 2.37 – 2.97 g/L |
| | | | Mechanical Instruments | 2.89 g/L | 2.59 – 3.19 g/L |
| | | | Atellica COAG 360 System | 2.59 g/L | 2.29 – 2.89 g/L |
| | 564810 564810A | Multifibren U | BFT II | 2.6 g/L | 2.3 – 2.9 g/L |
| | | | BCS XP | 2.8 g/L | 2.5 – 3.1 g/L |
| | | | Atellica COAG 360 System | 2.6 g/L | 2.3 – 2.9 g/L |
| | | Dade Thrombin Reagent | Sysmex CA/CS Systems | 2.58 g/L | 2.28 – 2.88 g/L |
| | | | Mechanical Instruments | 2.64 g/L | 2.34 – 2.94 g/L |
| | | | Atellica COAG 360 System | 2.50 g/L | 2.20 – 2.80 g/L |

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.

Sincerely yours,

This letter was created electronically and is valid without signature.

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Sysmex is a trademark of Sysmex Corporation, Japan.

FIELD CORRECTION EFFECTIVENESS CHECK

Dade Ci-Trol 1 – broader confidence interval for Fibrinogen using Dade Thrombin Reagent and Multifibren U are provided in the Table of Assigned Values

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Corrective Action PH-20-006 A OUS dated March 2020 regarding Dade Ci-Trol 1 – broader confidence interval for Fibrinogen using Dade Thrombin Reagent and Multifibren U are provided in the Table of Assigned Values.

Please read each 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 Corrective Action 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 **for the OUS letter the information will be filled in by the region).**

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