SIEMENS Healthineers

Urgent Field Safety Notice

PH-23-001-A-C OUS

February 2023

Sysmex® CA-500/CA-600 series

Prolonged Thrombin Time in Combination with Test Thrombin Reagent

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

Table 1. Test Thrombin Reagent Affected Product(s)

Reagent	Siemens Material Number (SMN)	Unique Device Identification (UDI) / GTIN	Lot Number	Manufacturing Date
Test Thrombin Reagent	10446598	00842768012716	Kit lots greater than or equal to 01038 until further notice	2022-01-24

Reason for Correction

The purpose of this communication is to inform you of an issue with the product indicated in Table1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Products GmbH received complaints regarding control recovery issues for Test Thrombin Reagent kit lots indicated in Table 1 on the Sysmex CA-500/600 series in combination with Control Plasma N, with results exceeding the upper limits of the Table of Assigned Values. Further investigations confirmed this observation. In case controls are found outside the assigned range no patient results must be reported.

Nevertheless, we also have performed studies with ostensibly healthy subjects and observed that a prolongation of greater than 20% may occur. The observed effect may be a combination of production material variance and Sysmex CA-500/CA-600 series specific application settings. Further investigation of this observation is ongoing.

No effect has been observed on the performance of Test Thrombin Reagent applications, supported by Siemens Healthineers, on other Sysmex coagulation instruments other than the Sysmex CA-500/CA-600 series.

Siemens Healthineers coagulation instruments are not affected by this issue.

According the Sysmex CA-500/CA-600 series OUS Reference Guide Version 4.02, no other control material other than Control Plasma N is currently validated and supported by Siemens Healthineers. Unfortunately, there is no workaround available to support the further operation of the Test Thrombin Reagent on the Sysmex CA-500/CA-600 series within the validated settings.

In case you are using the Thrombin Time application with Test Thrombin Reagent on the Sysmex CA-500/CA-600 series by validating your run with another control material, then it is recommended

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within the corresponding Reference Guide that, this is your responsibility and not validated nor supported by Siemens Healthineers.

Risk to Health

The issue is assessed as a negligible health risk.

If an invalid Quality Control occurs no tests on patient samples can be conducted and no patient results can be reported.

The failure of the Quality Control is apparent during the introduction of a new Test Thrombin Reagent lot.

Based on our investigation the differentiation of normal vs. pathological samples is working as intended. However, In the case that the Control Plasma N passes, ostensibly healthy patient should recover within the normal reference range according to Instructions for Use. Otherwise, laboratory established normal reference range may require a revalidation.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- For the products listed in Table 1, please perform the following steps:
    - The operation of Test Thrombin Reagent on the Sysmex CA-500/CA-600 series by employing Control Plasma N as quality control material is not recommended by Siemens until further notice.
    - We would like to reemphasize that the reference intervals may vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

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.

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

Sincerely yours,

This letter was created electronically and is valid without signature

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FIELD CORRECTION EFFECTIVENESS CHECK

Prolonged Thrombin Time in Combination with Test Thrombin Reagent

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice PH-23-001-A-C OUS dated February 2023 regarding prolonged Thrombin Time in combination with Test Thrombin Reagent. 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 Safety Notice 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 send a scanned copy of the completed form via email to XXXX@XXXX.

Or to fax this completed form to the Customer Care Center at XXXXXX.

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

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