SIEMENS

Urgent Field Safety Notice

BR-01317

January 2017

Sysmex CS-2000i, CS-2100i, CS-2500 and CS-5100 System

Possible risk for false negative reportable results with the INNOVANCE D-Dimer setting

Dear valued customer,

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

Table 1. Affected Product(s)

Assay	Assay application on Instrument	Siemens Material Number (SMN)
INNOVANCE® D-Dimer	Sysmex® CS-2000i	10471745
	Sysmex® CS-2100i	10488060
	Sysmex® CS-2500	11232203
	Sysmex® CS-5100	10768873

Reason for Correction

Siemens Healthcare Diagnostics has confirmed that under very rare circumstances a false negative result may be reportable.

The issue may only occur under the following conditions:

- The initial result is falsely flagged with an antigen excess error that triggers an automatic remeasurement in a 1/19 dilution.

AND

- The raw signal of the remeasurement is below the Limit of Blank (LoB) of the method.

Under such conditions the low remeasurement raw value may be strongly affected by the signal noise of the optical system and can generate an erroneous low optical raw value. This raw value will be corrected by the dilution factor and can be deduced from calibration curve in a false low range.

Emil-von-Behring Strasse 76
D-35041 Marburg; Germany
www.siemens.com/diagnostics

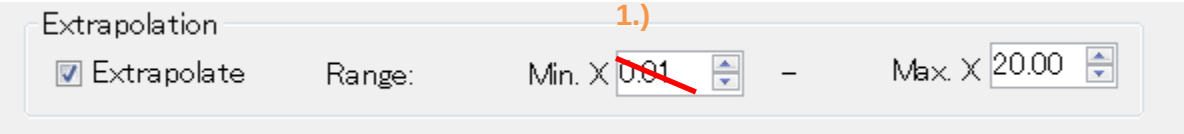
Risk to Health

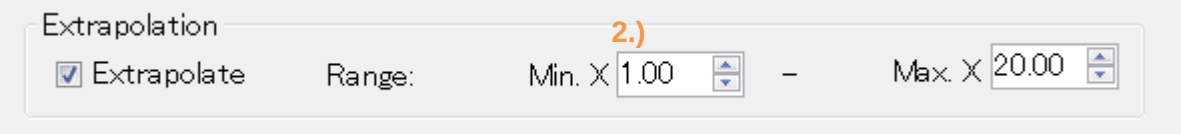
With a probability of occurrence below 10^{-6} the injury event frequency is far below that range and has been rated as extremely unlikely. Due to the general severity rating of the test parameter the overall health risk has been classified as low.

Actions to be Taken by the Customer

In order to overcome this issue, the threshold for “Min Range” of the extrapolation needs to be changed within the INNOVANCE D-Dimer setting.

Please start the CS-System’s Software and navigate to Settings > INNOVANCE D-Dimer > Assay Parameter “INN DDi”.
Change the current threshold for the “Min Range” from 1.) 0.01 to the new threshold 2) 1.00:





Please save and restart the CS-System’s Software. After the restart, the system will work with the new setting.

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Please review this letter with your Medical Director. Complete and return the Field Correction Effectiveness Check 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.

Dr. Norbert Dedner
Director
Quality Systems & Compliance

Eva-Maria Landmann
Marketing Manager
Global Marketing Hemostasis

FIELD CORRECTION EFFECTIVENESS CHECK

Sysmex CS-2000i, CS-2100i; CS-2500 and CS-5100

Possibility of false negative reportable results with INNOVANCE D-Dimer setting

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Medical Device Correction BR-01317 dated January 2017 regarding 'Sysmex CS-2000*i*, CS-2100*i*; CS-2500 and CS-5100 System - Possible risk for false negative reportable results with the INNOVANCE D Dimer setting'.

Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the Urgent Medical Device Correction instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Please fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.