

Potential Risk of Incorrect Assignment of Result with Sysmex Automated Blood Coagulation Analyzer CS-2100i/2000i (SMN 10488583/ 10488585)

Dear Sysmex CS-2100i/2000i customer,

Our records indicate that you are using a Sysmex® CS-2100i or CS-2000i Automated Blood Coagulation Analyzer in your laboratory.

The manufacturer of the device, Sysmex Corporation, has informed Siemens Healthcare Diagnostics about a software bug with Sysmex CS-2100i/2000i Analyzers. This could lead under certain circumstances to a result that is assigned to a wrong sample.

For details please find attached the Field Safety Notice issued by Sysmex Corporation (Attachment 1).

Please be advised to follow the instruction provided by Sysmex. Please confirm the receipt of the information provided under Sysmex Field Safety Notice issued November 2013.

If you have any questions or need assistance, please contact your local Siemens representative.

Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files and forward this information to all parties that may use a Sysmex® CS-2100i or CS-2000i Automated Blood Coagulation Analyzer.

Sysmex Europe GmbH has notified the German Competent Authority (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) and other European Authorities of this action.

Siemens Healthcare Diagnostics Products GmbH

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35041 Marburg, Germany

Phone: +49 6421 39-4511
www.siemens.com/diagnostics

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We apologize for any inconvenience that this situation has caused. Thank you for your continued support.

Sincerely yours,

Original signature is on file

Dr. Norbert Dedner
Director
Quality Systems & Compliance

Original signature is on file

Burcin Seza Gueney
Senior Product Manager
Global Marketing Hemostasis

Attachment 1 - Field Safety Notice issued by Sysmex Europe GmbH

EFFECTIVENESS CHECK

Potential Risk of Incorrect Assignment of Result with Sysmex Automated Blood Coagulation Analyzer CS-2100i/2000i

This response form is to confirm receipt of the information provided by Sysmex Corp. under the Field Safety Notice dated November 2013 regarding.

Please read the question and indicate the appropriate answer.

I have read, understood and implemented the information provided in the FSN issued by Sysmex in November 2013. Yes No

Name of person completing questionnaire:

Title:

Specify Instrument type
(CS-2000i or CS-2100i):

Institution:

Instrument Serial Number(s):

Street:

City:

State:

Phone:

PLEASE FAX THIS COMPLETED FORM TO your local Siemens representative.