SIEMENS Healthineers

Siemens Healthcare Diagnostics Products GmbH

Urgent Field Safety Notice

Sysmex 20-002 A OUS

September 2020

Sysmex Automated Blood Coagulation Analyzer

Potential risk of sample contamination by Emicizumab on Sysmex® Automated Blood Coagulation Analyzer

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Dear valued customer,

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

Table 1. Affected Product(s)

System	Siemens Material Number (SMN)
Sysmex CS-5100 System	10709128, 10713586.
Sysmex CS-2500 System	11239235.
Sysmex CS-2000i/2100i System	10471745, 10488064, 10488065, 10472158, 10488583, 10707684, 10471748, 10472159, 10488060, 10488062, 10488585.
Sysmex CA-7000 System	10285053, 10372356, 10455307, 10455350, 10455495, 10459327, 10459328, 10478989.
Sysmex CA-1500 System	10463887, 10489419, 10461841, 10461084, 10459322, 10459321, 10458690, 10458673, 10455611, 10455599 10455597, 10455596, 10455595, 10372380, 10372357 10285052, 10284916, 10462968, 10707453.
Sysmex CA-500/CA-600 System	10458668, 10458669, 10459323, 10461006, 10478981, 10285050, 10458670, 10459324, 10459325, 10463358, 10463884, 10453103, 10453105, 10450675, 10450676, 10458675, 10459326, 10459390, 10462116, 10463328, 10712040, 10712039

Sysmex Automated Blood Coagulation Analyzer

Potential risk of sample contamination by Emicizumab on Sysmex Automated Blood Coagulation Analyzer

Reason for Correction

The manufacturer of the Sysmex Automated Blood Coagulation Analyzers, Sysmex Corporation, Kobe, Japan, has informed Siemens Healthcare Diagnostics Products GmbH in August 2020 about a potential risk of sample contamination by Emicizumab (trade name Hemlibra®) from a sample containing this drug to the next sample analyzed on one of the Sysmex Automated Blood Coagulation Analyzers listed in the table above.

For details please find attached the Urgent Field Safety Notice 'FSCA 2004 FSN 2020-002', issued by Sysmex in August 2020 (Attachment 1) and follow the instructions given in this letter.

Further actions by Siemens Healthineers

Siemens Healthineers will support a mandatory assay update for the affected coagulation FVIII assays which will be provided by Sysmex on a Protocol Disk to update all Sysmex CS instruments. For the Sysmex CA-500/600 series, instruction to the manual setting update will be provided.

Furthermore, facultative assay updates for the APTT assays and ProC® global with Factor V Deficient Plasma will be provided for customers with a high number of samples that contains Emicizumab, if requested by the customers.

Please be advised to follow the instruction provided by Sysmex and confirm the receipt of the information to Siemens Healthineers by using the response form attached. Please do not contact Sysmex directly.

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 the affected Sysmex Automated Blood Coagulation Analyzers.

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

Sincerely yours,

i. V. Dr. Norbert Dedner
Senior Director
Quality Systems & Compliance

i.A. Lars Schmitt
Product Manager
Global Marketing Hemostasis

This letter was created electronically and is valid without signature.

Attachment 1: Urgent Field Safety Notice 'FSCA 2004 FSN 2020-002' issued by Sysmex in August 2020

Sysmex is a trademark of Sysmex Corporation.
ProC is a trademark of Siemens Healthcare Diagnostics

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

FIELD CORRECTION EFFECTIVENESS CHECK

Sysmex Automated Blood Coagulation Analyzer

Potential risk of sample contamination by Emicizumab medicine on Sysmex Automated Blood Coagulation Analyzer

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice Sysmex 20-002 A OUS dated September 2020 regarding a potential risk of sample contamination by Emicizumab on Sysmex Automated Blood Coagulation Analyzer

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 technical support representative.