Urgent Field Safety Notice

PH-21-003 A OUS

March 2021

BCS® XP System

Potential carryover of Emicizumab by patient samples

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

Table 1. BCS XP System Affected Product(s)

System	Siemens Material Number
BCS XP System	10459330, 10461894, 10470625, 11240019

Reason for Correction

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

Siemens Healthcare Diagnostics Products GmbH has confirmed that the BCS XP System may be affected by a potential Emicizumab carryover on patient samples.

Based on our investigations only the low Factor VIII clotting applications may be affected by this issue. Patient samples with Factor VIII concentrations above 15% of norm, measured in the normal Factor VIII clotting applications, are not affected.

Siemens Healthcare Diagnostics Products GmbH determined that an intensive washing after the measurement of an Emicizumab patient sample can eliminate the potential carryover. For further information, please see section “Additional Information”.

Risk to Health

Given the fact that only samples measured with the low Factor VIII applications directly after a sample from a patient treated with Emicizumab are affected by the carryover, the likelihood of this combination has been assessed to be very low.

However, there is still a very low possibility of overestimating samples measured with the low Factor VIII applications of patients with Hemophilia A if a carryover occurred.

Due to the extremely low expected probability of occurrence no general lookback procedure is recommended. In individual cases, when a low F VIII deviates from an anticipated F VIII level (only with the low application), a confirmation test should be concluded.

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D – 35041 Marburg, Germany

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Perform the instructions provided in Additional Information.
- Complete and return the Field Correction Effectiveness Check Form 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.

Additional Information

We recommend to measure patient samples with known Emicizumab treatment in batch mode followed by the intensive washing cycle described below.

After the measurement of a potential Emicizumab patient sample an intensive washing cycle of the sample probe is recommended, prior measuring any further sample with a low Factor VIII clotting application.

The intensive washing cycle is using a washing solution (Washing Solution for Coagulation Analyzers) in addition to the regular water rinse for the sample probe.

This additional washing step must be performed manually via the user software as described in the BCS XP System Instruction Manual, Chapter 11.1.4. This washing cycle cannot be implemented into the assay procedure for an automatic use.

In addition, results of Hemophilia patients measured with any F VIII low application should be carefully reviewed considering clinical history. In case of doubt, remeasuring is recommended.

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.

This letter was created electronically and is valid without signature

i. V. Dr. Norbert Dedner	i. A. Sandra Otto
Senior Director	Product Manager
Quality Systems & Compliance	Global Marketing

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FIELD CORRECTION EFFECTIVENESS CHECK

BCS XP System – Potential carryover of Emicizumab by patient samples

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice PH-21-003 A OUS dated March 2021 regarding BCS XP System – Potential carryover of Emicizumab by patient samples. 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: _____

Please send a scanned copy of the completed form via email to XXXX@XXXX (**for the US ONLY letter** use the following e-mail address: uscctsfcaecfax.team@siemens-healthineers.com, **for the OUS letter** the information will be filled in by the region).

Or to fax this completed form to the Customer Care Center at XXXXXX (**For US ONLY letter,** use the following phone number: (312) 275-7795, **for the OUS letter** the information will be filled in by the region) delete the Not Applicable text in yellow prior to sending.

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

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