

Urgent Field Safety Notice

BR-03115

April 2015

Siemens BCS / BCS XP System

Erroneously high Factor IX results with applications on BCS/BCS XP System at the lower end of the measuring range

Dear valued customer,

Our records indicate that you are using a Siemens BCS/BCS XP Automated Blood Coagulation Analyzer in your laboratory:

Table 1.

Instrument	Siemens Material Number (SMN)	Application
BCS	10454742 10454729	Application for Factor IX clotting assay using Actin, Actin FSL or Pathromtin SL
BCS XP	10461894 10470625	

Reason for Correction

This letter is to inform you about the situation with BCS / BCS XP analyzers regarding F IX assay determinations for Hemophilia B patients. Internal investigations showed discrepancies for Siemens BCS / BCS XP within dilution studies. We confirmed that samples at the lower measurement range were found elevated on the BCS/BCS XP system.

Risk to Health

Patient results in the lower measuring range may be misclassified within a higher Factor IX level.

Hemophilia B is characterized by deficiency in factor IX clotting activity that results in prolonged oozing after injuries, tooth extractions, or surgery, and delayed or recurrent bleeding prior to

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complete wound healing. The age of diagnosis and frequency of bleeding episodes are related to the level of factor IX clotting activity.

Patients that have been evaluated for hereditary factor IX deficiency disease for the first may have to be re-evaluated.

Follow your laboratory protocol regarding the need for review of previously reported patient results.

Actions to be taken by the customer

Please contact your local Siemens technical support representative for the following actions:

1. Please discontinue the use of the application "Factor IX with Pathromtin SL [34]" and use application "Factor IX with Pathromtin SL [463]" instead.

AND

2. Please discontinue the use of extrapolation at the lower end of measurement range for application "Factor IX with Pathromtin SL [463]" and application "Factor IX with Actin [467]".

AND

3. Do not report patient results below 30% F IX for application "Factor IX with Actin FSL [471]".

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 Siemens BCS /BCS XP Automated Blood Coagulation Analyzer.

We apologize for the inconvenience this situation has caused. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Sincerely yours,

Original signature is on file

Dr. Norbert Dedner
Director Quality Systems

Original signature is on file

Marlen Suller
Senior Director Global Marketing
Hemostasis

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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice BR-03115 dated April 2015 regarding BCS / BCS XP System. 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 BR-03115 instructions provided in this letter. Yes No
2. Are you using one of the below mentioned applications for measuring F IX on the BCS / BCS XP?
- | | |
|-------------------------------------|--|
| Factor IX with Pathromtin SL [34] | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Factor IX with Pathromtin SL [463]] | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Factor IX with Actin [467]] | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Factor IX with Actin FSL [471]] | Yes <input type="checkbox"/> No <input type="checkbox"/> |

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

Country:

Customer Sold To #:

Customer Ship To #:

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