

Urgent Field Safety Notice

BR-01216

November 2015

Sysmex® CA- / CS-Systems

Higher Occurrence of Irregular Curves with one Factor VIII Chromogenic Assay lot #44637

Dear Siemens customer,

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

Table 1. Sysmex CA- / CS-Systems Affected Product

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number
Factor VIII Chromogenic Assay	B4238-40	10445729	44637

Reason for Urgent Field Safety Notice

During recent investigations, Siemens Healthcare Diagnostics has observed that the above mentioned lot is showing an increased occurrence of irregular curves when used for measurement on Sysmex CA-/CS- instruments. This could lead under certain circumstances to an erroneously increased result with a Factor VIII chromogenic assay.

The use of the affected lot on BCS/ and BCS XP system is not affected by this issue.

Risk to Health

Some patient results may show a positive bias of more than 20% over the complete measuring range. Results that cross the medical decision points may be incorrectly assessed.

This letter should be reviewed with the treating physician or healthcare provider to ensure they are aware of the issue and can determine whether a re-evaluation of the patient is necessary.

Actions to be Taken by the Customer

If you are using the affected lot of Factor VIII Chromogenic Assay on a Sysmex CA-1500, CA-7000, CS-2000i, CS-2100i, or CS5100 instrument, please discontinue use.

Due to a different detection principle, the use on BCS and BCS XP is not affected and you can continue using the product on BCS / BCS XP.

Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

Review your inventory of this product to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the authorities.

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.

Original signature is on file

Dr. Norbert Dedner
Director
Quality Systems & Compliance

Original signature is on file

Marlen Suller
Senior Director
Global Marketing Hemostasis

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FIELD CORRECTION EFFECTIVENESS CHECK

Sysmex® CA- / CS-Systems

Higher occurrence of Irregular Curves with a Factor VIII Chromogenic Assay lot #44637

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics UFSN BR-01216 dated November 2015 regarding Factor VIII Chromogenic Assay. 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 Field Safety Notice instructions provided in this letter. Yes ☐ No ☐
2. Do you now have any of the noted product on hand? Please check inventories before answering. Yes ☐ No ☐

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.

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory that has been discarded	Replacement Quantity Required
Factor VIII Chromogenic Assay, B4238-40,10445729, lot 44637		

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.