

Urgent Field Safety Notice

12-25

June 2012

EasyLink™ Informatics System, Version 5.0, all SP versions

Result Number Format with Sysmex® CA Series Analyzer

Our records indicate that you are using the EasyLink™ Informatics System. Siemens Healthcare Diagnostics has discovered that when using a Sysmex® CA-7000 or CA-1500 coagulation analyzer with the EasyLink system, there is a potential for the EasyLink system to display and transmit to the LIS an incorrect result following the EasyLink systems application of the configured result number format.

The problem is encountered when the result number format configured on the Sysmex® CA-7000 or CA-1500 coagulation analyzer does not match the EasyLink system settings on the following page.

Incorrect results may be resident on the EasyLink system and sent to the LIS when the result number formats, for any assay configured on the Sysmex instruments and the EasyLink system, are not equal. This could result in mismanagement of a patient if the result is read from the EasyLink system or a correction is not made at the LIS (e.g. an INR result value of 7 would be converted to a 0.7).

Siemens recommends that the result number format configured on the Sysmex® CA-7000 or CA-1500 coagulation analyzers are set to match the configuration settings on the following page. Please note that using configurations different than those included with this letter could result in the reporting of incorrect results.

We recommend that you discuss the content of this letter with your laboratory director regarding the need to review any previous test results. After implementation of any changes to the CA Instrument configurations, please ensure that the values reported at the LIS and the EasyLink system are correct. If you have technical questions or concerns, please contact the Siemens Technical Solutions Center at 800-441-9250 for further assistance.

Please complete the attached Field Correction Effectiveness Check form and fax it to (302) 631-8467 **by June 22nd**. Please complete and fax the form to Siemens even if your lab has the correct configuration set or your CA Instruments are not connected to the EasyLink system. Please forward this notification to anyone to whom you may have distributed this product.

We apologize for the inconvenience that this situation has caused. Thank you for your patience and continued support.

Siemens Healthcare Diagnostics Inc.

P.O Box 6101
Newark, DE 19714-6101

www.siemens.com/diagnostics

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Sysmex® CA Series Analyzer Result Format Settings for Use with the EasyLink™ System

For each Assay in use, the settings on the Sysmex® CA-7000 or CA-1500 instrument (Calculation Parameter Settings) must be set as shown in the table below to ensure the results are accurately reported.

ASSAY	FORMAT	UNITS	Interface CODE
PT Seconds	XXX.X	sec	041
PT Percent	XXX.X	%	042
PT Ratio	XX.XX	Ratio	043
PT INR	XX.XX	INR	044
PT dFBG	XXX.X	mg/dl	045
APTT	XXX.X	sec	051
Fbg	XXX.X	mg/dl	062
Factor II	XXX.X	%	122
Factor V	XXX.X	%	152
Factor VII	XXX.X	%	172
Factor VIII	XXX.X	%	182
Factor IX	XXX.X	%	192
Factor X	XXX.X	%	202
Factor XI	XXX.X	%	212

ASSAY	FORMAT	UNITS	Interface CODE
Factor XII	XXX.X	%	222
LA 1	XXX.X	sec	271
LA Ratio	XX.XX	Ratio	273
LA 2	XXX.X	sec	281
LA 2 Percent	XXX.X	%	292
AT III	XXX.X	%	302
a2PI	XXX.X	%	312
Plg	XXX.X	%	322
PC	XXX.X	%	332
Heparin LMW	XX.XX	IU/ml	392
Heparin UF	XX.XX	IU/ml	402
TT	XXX.X	sec	511
D-Dimer	XX.XX	mg/l	612



FIELD CORRECTION EFFECTIVENESS CHECK

EasyLink™ Informatics System, Version 5.0, all SP versions

Result Number Format with Sysmex® CA Series Analyzer

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated June 2012 regarding the EasyLink™ Informatics System, Version 5.0, all SP versions.

Please complete the statement below by answering Yes or No. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page. Please complete and fax the form to Siemens even if your lab has the correct configuration set or if your CA Instrument(s) are not connected to the EasyLink system.

I have read and understood the information provided in this letter.

Yes ☐

No ☐

Name of person completing questionnaire:

Title:

Institution:

EasyLink System Serial
Number(s):

Street:

City:

State:

Phone:

PLEASE FAX THIS COMPLETED FORM TO THE SIEMENS TECHNICAL SOLUTIONS CENTER AT 302-631-8467 **BY JUNE 22nd**.

Siemens Healthcare Diagnostics Inc.

P.O Box 6101
Newark, DE 19714-6101

www.siemens.com/diagnostics

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