



**A facsimile from
NATIONAL DISTRIBUTION
& CONTRACTING, INC.**

Djana Milliken Compliance
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To: Compliance/Regulatory

*****URGENT*****

Date: 12/01/2015

3 pages + Cover

*****This is being faxed to the "bill to" account for your company. Please distribute to any/all branches.**

Regarding: CoaguChek XS Plus and XS Pro Systems – Error Message E-205

Comments:

Dear Distributor, attached is a letter we received from Roche Diagnostics regarding the error message E-205 on product number 04625315160. Our records indicate that you purchased this product from us. Please read attached letter and follow instructions given in letter. **Contact Roche Diagnostics directly for any other questions or concerns.**

Additionally, if you have distributed these products to your customers, please advise them of the letter.

Thanks,

Djana Milliken
Compliance Specialist
NDC, Inc.

15-202
11/19/15

Roche Diagnostics
9115 Hague Road, PO Box 50457
Indianapolis, IN 46250-0457 USA
Tel. + 1-317-521-2000
+ 1-800-428-5074



Analyzer Bulletin

CoaguChek® XS Plus and XS Pro Systems – Error Message E-205

Issue

The E-205 error message signals an interruption of the contact between the test strip and the instrument during a measurement. Recently, this error message has been observed upon the insertion of CoaguChek XS PT test strips (catalog number 04625315160) due to slight abrasions on the test strip gold foil. These slight abrasions can generate a contact interruption, especially when the test strip is inserted slowly by the operator.

Workaround

When the E-205 error message occurs immediately on the display, it could be due to the slight abrasions on the test strip. Simply remove the test strip and reinsert it into the instrument quickly. A single test strip can be reinserted into the instrument up to five times. Once the error message disappears, the test strip can be used and the measurement result is reliable.

OR

To entirely avoid the error message, use the following workaround:

1. Turn the instrument on by pressing the On/Off button.
2. Insert the test strip.
3. Start the measurement after the test strip is inserted by touching the Patient Test/Control Test button.



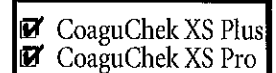
NOTE

Make sure that the instrument is not contaminated.

Clinical Significance

A false result is not possible and there is no risk to the patient.

over...



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Distributor Letter

Introduction

The enclosed documentation has been approved by Roche Diagnostics for distribution.

Action Required

Please copy the enclosed documentation and distribute it to your appropriate customers.

Questions

Please contact your Roche Diagnostics representative if you have questions about the information contained in this distributor letter or the enclosed documentation.

3068-00-1008

December 1, 2016

Please respond by
December 15, 2016

Roche

Acknowledgment of Receipt

Customer Information

Account No. _____

Account Name _____

Address _____

City/State/Zip _____

Contact Name _____

Phone No. _____

Fax No. _____

email _____

Inventory Information

Item number	Lot number
04625315160	

- I have read and understood the information within the accompanying notification. All relevant customers/personnel have been informed of its contents, any necessary actions taken and records retained as part of our documentation.
- We have inspected our inventory and have no product related to this recall

Returned Completed form to:

Fax #: Djana Milliken
Email: 615.229-6801
compliance@ndc-inc.com