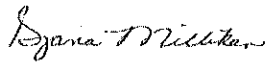




Delivering Efficiency to Healthcare



FAX COVER

From: <i>National Distribution & Contracting, Inc.</i> <i>Djana Milliken – Compliance</i> ***URGENT*** ***This is being faxed/emailed to the "bill to" account for your company. Please distribute to any/all branches.***	
To: <i>Purchasing or Regulations Department</i>	Date: <i>3/20/2016</i>
Pages: <u>4</u> (Including cover page)	
Regarding: <i>CoaguChek XS Plus System Bulletin</i>	
Comments: <i>Dear Distributor,</i> <i>Attached is a Bulletin we received from Roche Diagnostics regarding a serial number mismatch on item # 04800842160 and 05021537001. Our records indicate that you purchased one of these items from us. Please read attached bulletin and check your inventory for any affected product. If you have any questions please contact Roche Diagnostics directly at 1-800-428-4674. <u>It is very important that we receive a response, a record of receipt is very important in documentation of these types of notices.</u> Additionally, if you have distributed these products to your customers, please advise them of the correction.</i> <i>Thanks,</i>  <i>Djana Milliken</i>	

17-053
03/13/17

Roche Diagnostics

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+ 1-800-428-5074



Analyzer Bulletin

CoaguChek® XS Plus system – Serial Number Mismatch Between Meter Label and Meter Firmware

Issue

Roche Diagnostics has confirmed that as a result of Unique Device Identification (UDI) coding of the system, an issue was created where the CoaguChek XS Plus system serial number (SN) provided on the meter's label is different than the SN on the firmware of the meter. The SN on the label has one leading "0" more than the SN in the meter's firmware (e.g., label reads UQ00123027, firmware reads UQ0123027).

The 10 digit SN may cause a conflict when the firmware of the Data Management System (DMS) accepts only 9 digits, and the operator manually enters 10 digits.

The following products are affected by this issue:

Product	Catalog Number	Serial Number Range	Manufacture Date
CoaguChek XS Plus system	04800842160	UQ00123000 to UQ00124378	September 2016 onwards
COAGUCHEK XS PLUS CARE KIT	05021537001		

cobas IT 1000 is not affected by this issue.

Clinical Significance

This issue can only occur during an SN check while using a DMS with manual serial number entry. No incorrect results will be generated.

Workaround for Manually Entering the Serial Number in the DMS

If your CoaguChek XS Plus system is affected by this issue, omit the first "0" printed on the label when manually entering the serial number in the DMS.

over...



Actions Required

- If your CoaguChek XS Plus system is affected by this issue, omit the first "0" printed on the label when manually entering the serial number in the DMS.
- File this Analyzer Bulletin for future reference.

Questions

Please contact Roche Diagnostics Point-of-Care Technical Service at 1-800-428-4674 if you have questions about the information contained in this Analyzer Bulletin.

COAGUCHEK is a trademark of Roche.



3/20/2016

CoaguChek XS Plus System

Please fill out and fax/email this distributor form within 10 business days, even if you do not have the recalled product.

Please complete and fax to: 615-229-6801 Or email to: Compliance@ndc-inc.com

Acknowledgment of Receipt

Customer Information

Account No.	_____
Account Name	_____
Address	_____
City/State/Zip	_____
Contact Name	_____
Phone No.	_____
Fax No.	_____
Email	_____

Inventory Information

- 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

Completed by: _____
(Print Name /Signature/Date)

Returned Completed form to:

Fax #:
Email:

Djana Milliken
615.229-6801
compliance@ndc-inc.com

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