

## Urgent Field Safety Notice

<b>Notice Ref No:</b>	<i>&lt;reference number&gt;</i>
<b>Document Date:</b>	<b>13 July 2009</b>
<b>Type of Action</b>	<b>Field Corrective Action</b>

<b>PRODUCT AFFECTED:</b>	<b>CoaguChek XS; CoaguCheck XSPlus</b>
<b>SYSTEM AFFECTED:</b>	<b>CoaguChek XS; CoaguCheck XSPlus</b>
<b>MATERIAL NUMBERS:</b>	<b>04625412xxx; 04837975xxx; 04800842xxx</b>
<b>LOT NO (IF APPLICABLE):</b>	<b>All serial numbers</b>
<b>SUMMARY OF ISSUE:</b>	<b>Cleaning related malfunction of the meter leading to false high PT/INR results</b>
<b>ACTION REQUIRED:</b>	<b>Please modify your cleaning procedure</b>
<b>CONTACTS:</b>	<b>Technical Services: Country:</b>

**Reason for notice:**

Roche has confirmed the potential for falsely elevated INR test results with the CoaguChek XS meters. To date, a small percentage of meters (0,002% of all meters distributed) have been affected.

Cleaning and disinfecting with certain cleaning agents has been identified as the root cause, especially if applied near the test strip guide cover. Liquid entering the meter's housing can potentially cause damage to the meter.

This issue has been observed only in meters used by healthcare professionals and not by patients performing home testing (due to cleaning frequency, usage of certain agents and drying time before running the next test).

If a meter is affected by this problem, in the vast majority of cases it shows an error message and no test result is displayed. In rare cases, a positive bias of the patient's test result with or without an error message associated to the result might be displayed.

If the test results are biased, the significance cannot be predicted although it will always be towards a higher PT/INR value.

**Action required:**

When cleaning/disinfecting the device follow the attached “Important Note”.

We apologize for any inconvenience this problem may cause you.

The undersign confirms that this notice has been notified to the appropriate  
Regulatory Agency  
(Closing paragraph)  
Signature



# Important Note

## **For Healthcare Professionals: Cleaning/Disinfecting Agents and Procedures**

Please follow the procedures below to clean and disinfect the meter. Failure to follow the procedures may cause malfunction of the device.

**Do not use sprays of any sort!**

Cleaning/Disinfection the meter's housing

- Ensure that the blue test strip guide cover (measurement chamber cover) remains tightly closed while cleaning the housing.
- Do not let liquid accumulate near any opening. Make sure that no liquid enters the meter.
- Ensure that swab or cloth is only damp, not wet.
- Wipe away residual moisture and fluids after cleaning the housing.
- Allow wiped areas to dry thoroughly for at least 15 minutes before performing a test.

Cleaning/Disinfecting the meter's test strip guide (measurement chamber)

- Use gloves while cleaning/disinfecting.
- Use only > 99 % Isopropanol, > 96 % Ethanol or a mixture of 1-propanol / 2-propanol / ethanol / water (e.g. Bacillol®Tissues) as cleaning/disinfecting agents.
- When cleaning/disinfecting, hold the meter upright with the test strip guide facing down.
- Ensure that swab or cloth is only damp, not wet
- Apply agent for the minimum required contact time (refer to the cleaning/disinfecting agent's labelling; e.g. 30 sec). Wipe away residual moisture and fluids
- Let the inside of the test strip guide dry for about 15 minutes before re-attaching the test strip guide cover and start testing again.

**Please contact your local Roche customer service if**

- **error 4 appears when turning on the instrument 1<sup>st</sup> time after cleaning/disinfecting or**
- **error 8 appears during the 1<sup>st</sup> measurement after cleaning/disinfecting**

Useful tips on how to minimize the risk of contaminating the meter with blood: apply blood via side-dosing directly from the fingertip. If pipettes or syringes are used, the blood volume should not exceed 10 µl.