URGENT MEDICAL DEVICE CORRECTION

13-099
05/16/13

Healthcare Professionals
CoaguChek® XS, CoaguChek XS Plus, and CoaguChek XS Pro Meters
– Potential for Elevated INR Test Results When “ERROR 6” Message is Displayed Repeatedly

Issue
Roche has confirmed the potential for an undetected elevated INR test result with the CoaguChek XS, CoaguChek XS Plus, and CoaguChek XS Pro meters. In rare cases, instead of a value, an “ERROR 6” message is displayed.

“ERROR 6” messages are generally due to an activation of the system fail-safe mechanisms that are designed to prevent the release of wrong measurement results.

However, patients who are under treatment with Warfarin in combination with antibiotics and/or chemotherapeutics, which could potentially lead to extremely high coagulation times (> 10 INR), may in rare cases receive repeated “ERROR 6” messages instead of an INR value.

If the “ERROR 6” message is displayed repeatedly, use an alternative method to determine an INR result. Patient self-testers are being asked to contact their physician without delay if “ERROR 6” is displayed repeatedly on their meter.

The following meters are affected by this issue:

<table>
<thead>
<tr>
<th>Meter</th>
<th>Catalog Number</th>
<th>Serial Numbers Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoaguChek XS PS1 Care Kit</td>
<td>04837738001</td>
<td>All Serial Numbers</td>
</tr>
<tr>
<td>CoaguChek XS Kit USA</td>
<td>04625412160</td>
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<tr>
<td>CoaguChek XS Professional Care Kit</td>
<td>04837975001</td>
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<tr>
<td>CoaguChek XS Plus Care Kit</td>
<td>05021537001</td>
<td>&lt;UQ0900000</td>
</tr>
<tr>
<td>CoaguChek XS Pro Care Kit</td>
<td>05530199160</td>
<td>&lt;U76011000</td>
</tr>
</tbody>
</table>

To date, only one case of high INR values related to the “ERROR 6” issue has been reported using the CoaguChek XS meter. This case was outside of the United States. There have been no cases reported with the CoaguChek XS Plus or CoaguChek XS Pro meters to date.
The CoaguChek XS PT Test Strip package inserts and user's manual for all CoaguChek XS meter systems are being updated to provide additional "ERROR 6" message information and actions for patient self-testers. Updated versions will be available on the www.poc.roche.com website by the end of June 2013.

**Clinical Significance**

High INR values above the normal upper end of the range are associated with an increased risk of bleeding. When high INR results are undetected by a patient self-tester, the problem may lead to a delay in medical intervention.

**Enclosure**

Faxback form 5059-00-0513

**Actions Required**

- If an "ERROR 6" message is displayed repeatedly on the CoaguChek XS, CoaguChek XS Plus, or CoaguChek XS Pro meters for the same patient, use an alternative method to determine INR results for that specific patient.
- If your facility has distributed the affected product to another site, please ensure this Urgent Medical Device Correction (UMDC) is provided to that site.
- Complete the attached fax form and fax it to 1-855-208-4042.
- File this UMDC for future reference.

**Questions**

Please contact your Roche Account Manager or Roche Diagnostics Point of Care Technical Service, 24 hours a day, seven days a week at 1-800-428-4674 if you have questions about the information contained in this UMDC.

This UMDC is being conducted in cooperation with the U.S. Food and Drug Administration (FDA).

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Events Reporting Program: Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or call FDA 1-800-FDA-1088.

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