URGENT MEDICAL DEVICE CORRECTION UPDATE

09-111U2
12/15/09

Attention: Healthcare Professionals

CoaguChek XS and CoaguChek XS Plus Meters — Cleaning Related Malfunction of Meter Potentially Leading to Falsely Elevated PT/INR Results

Update

Urgent Medical Device Correction 09-111 has been updated with the following:

- Modified disinfecting solutions for the meter outer housing
- Cleaning Verification section added
- Meter Modifications section added
- Meter Replacement section added

Please note, updates are indicated by black bars in the margin.

Issue

Internal investigations have confirmed that previously recommended cleaning procedures can lead to falsely elevated PT/INR results on CoaguChek XS meters with serial numbers below UP0400000 and CoaguChek XS Plus meters with serial numbers below UQ0040000. In rare circumstances, these procedures can cause electrical bridging between heater pins in the CoaguChek XS and CoaguChek XS Plus meters. The electrical bridging between the pins may cause the instrument to read the incubation temperature as having reached 37 °C (98.6 °F), when in reality the heater temperature is lower. This causes coagulation to start at too low of a temperature, leading to falsely elevated PT/INR results.

If a meter is affected by this problem, in the vast majority of cases it shows an error message (**error message 4 or 8**) and no test result is displayed.

- **error 4**: the test strip is unusable
- **error 8**: an error occurred during the internal diagnostic test

In rare cases, a positive bias of the patient's test result with or without an error message is displayed.

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 cause damage to the meter.

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Clinical Significance

Positive deviations of > 30% are possible; therefore, there is a remote risk for incorrect treatment due to falsely elevated results.

Please consult with the physician or pathologist at your facility to determine specific clinical implications for your patients and to determine if any clinical intervention is needed for patients that have been treated based on these results.

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Updated Meter Cleaning Instructions

In order to avoid the issue outlined in this Urgent Medical Device Correction (UMDC) Update, Roche Diagnostics recommends separate cleaning instructions for cleaning/disinfecting the meter housing and cleaning the meter test strip guide. All cleaning and disinfecting solutions detailed in this UMDC Update are commonly available at medical supply distributors or drug stores. Failure to follow these procedures may cause a cleaning related malfunction of the meter.

NOTE

These updated cleaning procedures replace the current procedures in your CoaguChek XS or CoaguChek XS Plus user manuals.

WARNING

Do not use sprays of any sort!

WARNING

Ensure that the swab or cloth is only damp, not wet!

Meter Housing (Outside of Meter)
- 70% isopropyl alcohol
- 10% bleach

Meter Test Strip Guide (Measurement Chamber)

Remove the test strip guide cover before cleaning
- 91% or 99% isopropyl alcohol
- **Discontinue 70% isopropyl alcohol or 10% bleach solution**

Cleaning/Disinfecting the Meter Housing

- Use only the following items for cleaning/disinfecting the CoaguChek XS or CoaguChek XS Plus meter housing for a contact time of > 1 minute:
  - **70% isopropyl alcohol**
  - **10% Sodium hypochlorite (1 part bleach to 9 parts de-ionized water, made fresh every 24 hours)**
  - **NOTE: Do not use any other disinfectants/cleaning solutions on the meter housing.**
- **Discontinue use of 91% alcohol on the meter housing.**
- Ensure that the blue meter test strip guide cover remains tightly closed while cleaning the housing.
- Wipe the meter housing thoroughly while avoiding the meter test strip guide (measurement chamber).
- Let the disinfectant/cleaning solution sit on the meter for at least one minute.
- Make sure that no liquid enters the meter or accumulates near any opening.
- Wipe away residual moisture and fluids after cleaning the housing.
- Allow wiped areas to dry for at least 15 minutes before performing a test.

Cleaning the Meter Test Strip Guide (Measurement Chamber)

NOTE

Discontinue use of 70% isopropyl alcohol or 10% bleach solution, including CoaguWipe Bleach Towels for cleaning/disinfecting the meter test strip guide.

- **Use only 91% isopropyl alcohol or 99% isopropyl alcohol to clean the CoaguChek XS or CoaguChek XS Plus test strip guide.**
- **Do not use any other cleaning solutions on the test strip guide. Use of other cleaning solutions could result in damage to the meter.**
- Remove the test strip guide cover.
- Hold the meter upright with the test strip guide facing down (see picture below). This will help prevent fluid from entering the meter.
- There are different types of isopropyl alcohol. Please note that only 91% isopropyl alcohol or 99% isopropyl alcohol can be used on the test strip guide. Any other isopropyl alcohol cannot be used on the test strip guide without risk to the meter.

Correct

Incorrect

- Ensure the swab is only damp, not wet.
- Wipe the test strip guide area.
- Let the cleaning solution sit for at least one minute.
- Wipe away residual moisture and fluids.
- Let the inside of the test strip guide air dry for at least 15 minutes before re-attaching the test strip guide cover and start testing again.

Please contact Roche Diagnostics Point of Care Technical Service at 1-800-820-0995 if you have any questions about the cleaning/disinfecting solutions detailed in this UMDC Update.

Useful Tips

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.

Cleaning Verification

The CoaguChek XS System and the CoaguChek XS Plus System are equipped with a two level on-board quality control test. To verify the meter after cleaning, an additional system check can be performed with a single level of optional external control (CoaguChek XS PT Control for the CoaguChek XS system or CoaguChek XS Plus PT Controls for the CoaguChek XS Plus system). A limited supply of the CoaguChek XS PT Control will be available in the first quarter (Q1) of 2010. Contact your Roche Diagnostics sales representative for information on availability.

Meter Modifications

Roche Diagnostics is adding safeguards to the meter to prevent the potential for cleaning related malfunctions. Meters equipped with the following modifications will be available beginning the first quarter (Q1) of 2010:

- new firmware that provides an additional fail-safe for cleaning related malfunctions (**error 9**). This new fail-safe feature produces an **error 9** message prior to blood application in the event of a cleaning related malfunction
- heater subassembly modifications to prevent cleaning solutions from contacting the heater pins

CoaguChek XS meters equipped with the modifications will begin with serial number UP0400000. CoaguChek XS Plus meters equipped with the modifications will begin with serial number UQ0040000.

Meter Replacement

Once available, Roche Diagnostics will replace CoaguChek XS meters with serial numbers below UP0400000 and CoaguChek XS Plus meters with serial numbers below UQ0040000 with meter(s) that have the modifications described above. Roche Diagnostics will begin shipping replacement meters in Q1 of 2010.

Continue to use your existing CoaguChek XS or CoaguChek XS Plus meter(s) along with the updated cleaning/disinfecting procedures outlined in this UMDC Update until you receive your replacement meter(s).

Actions Required

- Please call 1-866-625-5325 to arrange the replacement of your meter(s).
- Continue to use your existing CoaguChek XS or CoaguChek XS Plus meter(s) along with the updated cleaning/disinfecting procedures outlined in this UMDC Update.
- Contact Roche Diagnostics Point of Care Technical Service at 1-800-820-0995 if :
  - **error 4** appears when turning on the instrument the first time after cleaning/disinfecting,
  - **error 8** appears during the first measurement after cleaning/disinfecting,
  - **error 9** appears, or
  - if you have questions regarding the reliability of your results.
- For subsequent **error 4** or **error 8** messages unrelated to cleaning, follow the instructions provided in the User's Manual. If the error persists, contact Roche Diagnostics Point of Care Technical Service at 1-800-820-0995.
- File this Urgent Medical Device Correction (UMDC) Update for future reference.
- Discard Urgent Medical Device Correction 09-111.

Questions

Please contact Roche Diagnostics Point of Care Technical Service at 1-800-820-0995 if you have questions about the technical information contained in this Urgent Medical Device Correction Update. Please call 1-866-625-5325 for questions regarding the replacement of your meter(s).

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

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Adverse Event Reporting program online [at www.fda.gov/MedWatch/report.htm], by phone [1-800-FDA-1088], or by returning the postage-paid FDA form 3500 [which may be downloaded from www.fda.gov/MedWatch/getforms.htm] by mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787 or fax [1-800-FDA-0178].

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