

URGENT MEDICAL DEVICE CORRECTION For Clients-Patients



Roche Support Network | Roche Care Center
201 Armand-Frappier Blvd, Laval, Quebec, H7V 4A2

Date	December 2018	RR201826-Version2
Subject	Update - CoaguChek XS strips standardized with WHO rTF16: Deviation of high INR values	
Systems	Coaguchek® XS, Coaguchek® XS Plus, Coaguchek® XS Pro	
Attachment	N/A	

Products name	Product no	UPC / EAN code	Concerned Lots
CoaguChek XS PT test strips – 6 tests	04625374190	401563 093679 3	From 272167 (S_303) up to 334498 (S_343)
CoaguChek XS PT test strips – 24 tests	04625358019	401563 001991 5	
	04625358172	076133 361538 33	
CoaguChek XS PT test strips – 2 x 24 tests	04625315019	401563 093686 1	
	04625315172	076133 361538 40	

Update

Roche would like to provide you with an update on the Urgent Medical Device Correction RR201826-regarding the CoaguChek XS strips limitation of use in high INR values, and clarify the action items.

Please be advised that this Urgent Medical Device Correction RR201826 **is not** a product removal, as the product itself is not defective and can be used with a workaround provided in this communication. (Section *Workaround for Product users*)

- *Values are reliable from 0.8 to 4.5 INR, since the calibration data covers this measuring range very well and are independent from the used WHO reference material (rTF/09 or rTF/16).*
- *There is no medical risk with the difference caused by the new WHO standard (rTF/16) in the therapeutic ranges <4.5 INR.*
- *This is due to a limitation in the interpretation of values outside the therapeutic range (> 4.5 INR)*
- *Additionally, there is already a special recommendation in the package insert for values outside of the therapeutic range:*

“If the measured PT result is unusually high or low repeat the test. If the PT result is still outside the therapeutic range specified by your treating physician, immediately contact your physician and ask for the appropriate (anticoagulant) measures to take in order to reduce risks that could be encountered due to excessive anticoagulation (danger of bleeding) or insufficient anticoagulation (risk of thrombosis).”

Subject

Since the introduction of CoaguChek test strips calibrated with the new WHO reference Thromboplastin, rTF/16, Roche Diagnostics has received an increased number of complaints regarding deviations of CoaguChek test strips against non-Roche controls as well as laboratory methods.

Investigation

In-depth analysis has been initiated in order to determine the cause:

Our findings:

- For values within the common therapeutic ranges (up to 4.5 INR) and covered by the new (rTF/16) WHO standard (1.5-4.5 INR) a small positive bias was observed when we compared the new CoaguChek test strips against Innovin-based thromboplastin from the previous (rTF/09) reference WHO standard. This bias is caused by the differences between the previous (rTF/09) and the new (rTF/16) WHO reference standards and was expected to be seen.
- For values >4.5 INR an unexpected increasing positive bias was found between CoaguChek test strips referenced to the latest WHO rTF/16 and Innovin-based laboratory methods referenced to rTF/09.

Workaround for Product Users

You can continue to use your CoaguChek device as you have done before. However, in order to prevent any risk, we recommend the following:

- If you are using **one of these lots** ($\geq 272167 \leq 334498$) and result values are:
 - ≤ 4.5 INR: Values are valid and can be used without lab comparison
 - > 4.5 INR: Values should be compared with a laboratory method or with unaffected CoaguChek test strips lots. ***Patients should contact their Physician for specific instructions.***

In addition, the testing frequency shall be increased according to local medical guidelines until results in the therapeutic range of that individual are obtained until recalibrated material is available.

Refer to the method sheet in section “How to proceed if test results are outside the therapeutic range”

“If the measured PT result is unusually high or low repeat the test. If the PT result is still outside the therapeutic range specified by your treating physician, immediately contact your physician and ask for the appropriate (anticoagulant) measures to take in order to reduce risks that could be encountered due to excessive anticoagulation (danger of bleeding) or insufficient anticoagulation (risk of thrombosis).”

Resolution

Roche has decided to re-calculate the calibration for upcoming CoaguChek strip lots according to the previous WHO standard (rTF/09).

CoaguChek XS PT Test lot 334499 - code key S 344 will be the first lot recalibrated to rTF/09 which will not have limitation in results values > 4.5 INR up to 8.0 INR.

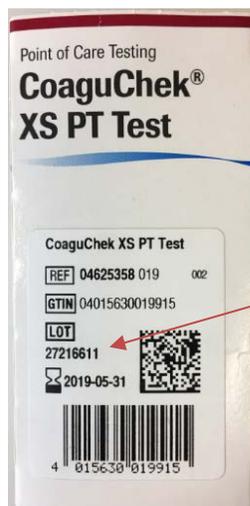
! Once you start to use the CoaguChek XS PT Test strips lots \geq 334499, you can return to usual testing and treatment procedure

Please Note:

- ☞ **There will not be any replacement of CoaguChek XS PT Test strip lot as the current lots are still good and can be used applying the recommended workaround provided in this communication.**
- ☞ **The new CoaguChek XS PT Test lot is not available yet, it will be distributed normally as the previous inventory is depleted. There will not be any credit nor replacement of the current lots.**
- ☞ **Until the availability of new lots, you can continue to use current strips lots (from 272167 (S_303) - up to 334498 (S_343)) following the workaround provided above in this Urgent Medical Device Correction.**

How to identify CoaguChek test strip lot/code chip number

The **Strip lot number** is printed on the label, which is applied to the test strip box at manufacturing:



The first **6 digits** correspond to the **lot number**,
the last **2 digits** correspond to a **batch number**.
In our example : the lot number is : **272166**

The **Code chip number** is printed on the code chips (as shown below).



Action for CLIENTS-PATIENTS

1. Read and understand this Urgent Medical Device Correction RR201826 –Clients-Patients.
 2. Implement the recommended *Workaround for Product Users* provided above, when using **one of these lots** ($\geq 272167 \leq 334498$).
 3. **Once you start to use the CoaguChek XS PT Test strips lots ≥ 334499 , you can return to usual testing and treatment procedure**
 4. ***You don't have to reply to Roche.***
- Please keep this document for future reference

Attention!

Sites-clinics, patients or clients purchasing their products from pharmacies or distributors need to contact their supplier directly.

Questions

For CoaguChek support or inquiry please do not hesitate to contact the Roche Care CoaguChek Support at 1-877-426-2482.

Thank you for your continued support of Roche Diagnostics.