

Consumer Letter

(CoaguChek XS PT Test PST, CoaguChek XS PT Test, CoaguChek PT Test)



Urgent Field Safety Notice

<Enter address here>

Roche Diagnostics Limited,

Date: 22/08/2018

Ref: PFSN18 Deviations of high (>4.5) CoaguChek INR values due to calibration with WHO reference standard rTF/16 SBN-CPS-2018-014.

We are writing to inform you about an issue concerning your CoaguChek system and test strips. Please read this information carefully.

Dear Customer,

In order to ensure that your CoaguChek values can be compared to values of other devices (e.g. laboratory systems, Point-of-Care systems in your GP office/Coagulation clinic) we calibrate our test strips against the standard from the World-Health-Organization (WHO). This standard was renewed in 2016. Although manufacturers are not obliged to standardize against the newest standard, as a pioneer for the monitoring of so called "Blood Thinners" Roche Diagnostics decided to do so.

Roche Diagnostics has received an increase in complaints regarding deviations against laboratory methods during the last weeks. Therefore, we initiated an in-depth analysis in order to determine the reasons for the observed differences.

The results of the analysis were:

- For values between 0.8 and 4.5 INR: No significant differences are seen and your CoaguChek is reliable.
- For values above 4.5 INR: Greater than expected deviations to the laboratory methods were seen.

What does that mean to me as a patient self-tester?

Each patient has a so called "therapeutic range" she/he should be compliant to. The therapeutic range is defined by the indication you are receiving "Blood Thinners" (e.g. Atrial fibrillation, heart valve, VTE etc.) for. None of the medically used therapeutic ranges exceed the above mentioned value of INR 4.5. Therefore, your system is delivering reliable results for your relevant therapeutic range.

However, according to the package insert you should contact your physician every time you are out of your therapeutic range:

CoaguChek XS PT Test:

"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)."

CoaguChek XS PT Test PST:

“If the measured result is outside the therapeutic range specified by your treating physician, repeat the test. If the result is still outside the therapeutic range immediately contact your physician and ask for the appropriate (anticoagulant) measures to take.”

Therefore, the limitation caused by this issue should be minimal, except for the fact that you should ask your health care professional for a laboratory cross-check for values above 4.5 INR.

You can continue using your CoaguChek device as you have done before with one limitation: As soon as you measure values above 4.5 INR, please contact your health care professional and ask for parallel testing with a laboratory method in order to decide on your further medication.

Which are the affected test strip lots?

The following lot numbers may be used up to an INR of 4.5. If the values exceed an INR of 4.5, please contact your health care professional.

Product	REF-Number (found on your test strip box)	Lot Number (only valid up to 4.5 INR)
CoaguChek XS PT Test	04625315019	272167 – 334498
	04625358019	
	04625374190	
CoaguChek XS PT PST Test	07671679190	272167 – 334498
	07671687019	

Table 1: Lot numbers affected by the limitation

Will this limitation be forever?

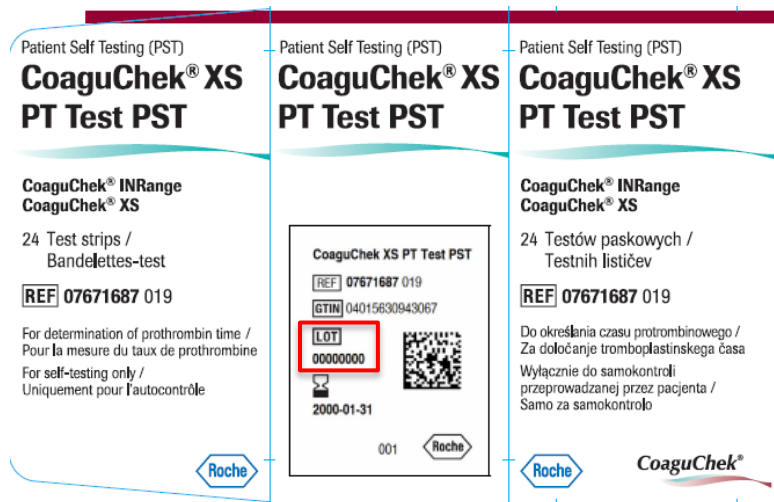
No – Roche Diagnostics has already started to produce new CoaguChek test strips, which will not have this limitation anymore and those strips will be available from **November 2018** as follows:

REF-Number	Product Name	From Lot Number and (Code Key)
07671679190	CoaguChek XS PT Test PST, 6 tests	334499 (S_344)
07671687019	CoaguChek XS PT Test PST, 24 tests	334499 (S_344)
04625374190	CoaguChek XS PT Test, 6 tests International	334499 (S_344)
04625358019	CoaguChek XS PT Test, 24 tests	334499 (S_344)
04625315019	CoaguChek XS PT Test, 2 x 24 tests	334499 (S_344)

Table 2: Availability of new lots

How do I recognize which CoaguChek test strip lot/code chip number I have?

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



**Example for box only*

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



Who can I call for more advice?

Please contact your Roche Diagnostics Customer Care Centre under the following numbers:

Calling from the UK call 0808 100 7666, if calling from Ireland call 1 800 99 2868.

Please choose **option 4** to reach our Support Team.

We apologise for any inconvenience caused by this issue to you.

Sincerely,

Roche Diagnostics



ACKNOWLEDGEMENT

URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

Field Safety Notice Ref No: PFSN18 Deviations of high (>4.5) CoaguChek INR values due to calibration with WHO reference standard rTF/16 SBN-CPS-2018-014

Date: 22/08/2018

Type of Action: Field Safety Corrective Action (FSCA)

Product :

CoaguChek XS PT Test PST

CoaguChek XS PT Test

System:

CoaguChek INRange

CoaguChek XS

Customer Name

Address:

I acknowledge receipt of this Field Safety Notice Letter and have read, understood and implemented its content. Please return this form using the pre-paid label and envelope provided

Name:

Signed:

Date:

This action is being conducted with the knowledge of the Medicines and Healthcare Products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.

Roche Diagnostics operates a vigilance system that complies with the IVD Directive 98/79 EC

A copy of this notice can also be found on www.coaguchek.co.uk

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If you require any further information please contact our

Technical Support Hotline

UK: 0808 100 7666 (option 4)

Ireland: 1 800 99 2868 (option 4)