

Consumer Letter

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



Urgent Field Safety Notice

<Enter address here>

Location, Date

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.

[COUNTRY ACTION: You are allowed to adopt the letter to your country specific situation, i. e. to insert or to remove the green text blocks below ([For countries performing patient-self testing] and [For countries performing patient-self management]) according to local procedures.

[For countries performing patient-self testing] 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 of the fact that you should ask your health care professional for a laboratory cross-check for values above 4.5 INR.

[For countries performing patient-self management] 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 | Lot Number (only valid up to 4.5 INR) |
|---------------------------------|--------------|---|
| CoaguChek XS PT Test | 04625315xxx* | #272167 – 334498 |
| | 04625358xxx* | |
| | 07797826160 | |
| | 04625374xxx* | |
| CoaguChek XS PT PST Test | 07671679190 | #272167 – 334498 |
| | 07671687xxx* | |
| | 07762798xxx* | |

Table 1: Lot numbers affected by the limitation

[COUNTRY ACTION Note: xxx* refers to the different language versions → countries: Please insert your respective SPV number, remove* and the remaining REF numbers.]

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 **beginning / mid of October 2018** as follows:

| REF-Number | Product Name | Lot Number (Code Key) | Availability on stock (Mann- heim) |
|-------------|---|--------------------------|--|
| 07671679190 | CoaguChek XS PT Test PST, 6 tests | ≥334499 (S_344) | CW 40 |
| 07671687003 | CoaguChek XS PT Test PST, 24 tests | ≥334499 (S_344) | CW 40 |
| 07671687016 | CoaguChek XS PT Test PST, 24 tests | ≥334499 (S_344) | CW 40 |
| 07671687019 | CoaguChek XS PT Test PST, 24 tests | ≥334499 (S_344) | CW 42 |
| 07671687070 | CoaguChek XS PT Test PST, 24 tests | ≥334499 (S_344) | CW 40 |
| 07671687170 | CoaguChek XS PT Test PST, 24 tests | ≥334499 (S_344) | CW 42 |
| 07762798003 | CoaguChek XS PT Test PST, 2 x 24 tests | ≥334499 (S_344) | CW 40 |
| 07762798016 | CoaguChek XS PT Test PST, 2 x 24 tests | ≥334499 (S_344) | CW 40 |
| 04625374160 | CoaguChek XS PT Test, 6 tests USA | ≥334499 (S_344) | CW 42 |
| 04625374190 | CoaguChek XS PT Test, 6 tests International | ≥334499 (S_344) | CW 40 |
| 04625358003 | CoaguChek XS PT Test, 24 tests | ≥334499 (S_344) | CW 42 |
| 04625358016 | CoaguChek XS PT Test, 24 tests | ≥334499 (S_344) | CW 42 |
| 04625358019 | CoaguChek XS PT Test, 24 tests | ≥334499 (S_344) | CW 40 |
| 04625358070 | CoaguChek XS PT Test, 24 tests | ≥334499 (S_344) | CW 42 |
| 04625358170 | CoaguChek XS PT Test, 24 tests | ≥334499 (S_344) | CW 42 |

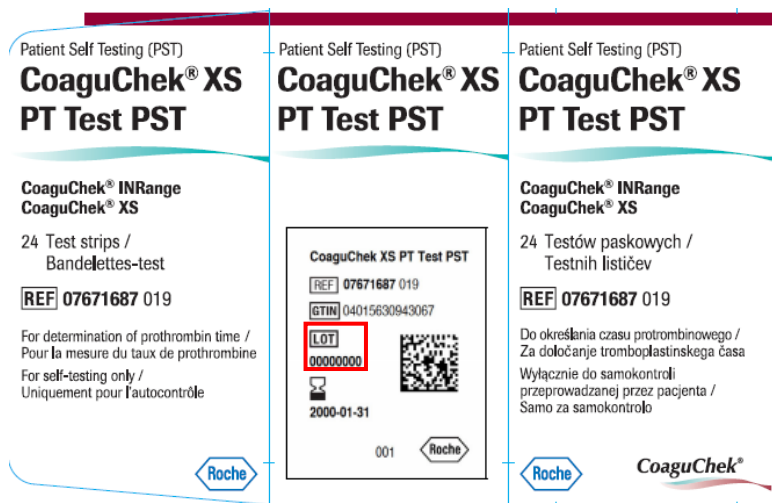
| | | | |
|-------------|------------------------------------|-----------------|-------|
| 04625358172 | CoaguChek XS PT Test , 24 tests | ≥334499 (S_344) | CW 40 |
| 07797826160 | CoaguChek XS PT Test, 24 tests | ≥334499 (S_344) | CW 42 |
| 04625315003 | CoaguChek XS PT Test, 2 x 24 tests | ≥334499 (S_344) | CW 42 |
| 04625315016 | CoaguChek XS PT Test, 2 x 24 tests | ≥334499 (S_344) | CW 40 |
| 04625315019 | CoaguChek XS PT Test, 2 x 24 tests | ≥334499 (S_344) | CW 40 |
| 04625315070 | CoaguChek XS PT Test, 2 x 24 tests | ≥334499 (S_344) | CW 42 |
| 04625315160 | CoaguChek XS PT Test, 2 x 24 tests | ≥334499 (S_344) | CW 42 |
| 04625315172 | CoaguChek XS PT Test, 2 x 24 tests | ≥334499 (S_344) | CW 40 |

Table 2: Availability of new lots

[COUNTRY ACTION. Please remove REF number not available in your country]

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:



LOT-Number

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



Code Chip Number

Who can I call for more advice?

Please contact your Roche Diagnostics Customer Care Center under the following number: **[COUNTRY ACTION: insert number]**

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

Sincerely,



[COUNTRY ACTION: Insert signatures and company name]