CoaguChek XS PT Test

REF **04625374160** Σ 6 SYSTEM CoaguChek® XS

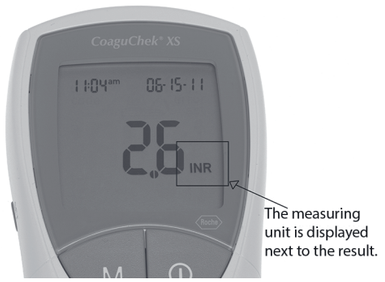
PERSONAL USE

Purpose

The CoaguChek XS PT Test strips are part of the CoaguChek XS System. The CoaguChek XS System measures blood-clotting time for people who are taking anticoagulation medications such as Coumadin® or warfarin.
The CoaguChek XS System uses blood from a fingerstick. The system is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor. Users should be stabilized on anticoagulation medications such as Coumadin or warfarin prior to self-testing with the CoaguChek XS System.

Caution: These test strips are for use outside the body only. Do not eat the test strips.

Caution: The CoaguChek XS Meter is pre-set to display results in the International Normalized Ratio (INR). The meter is also capable of displaying results in seconds (displayed on meter as Sec) and % Quick (displayed on meter as %Q) (a measuring unit used mainly by healthcare professionals in Europe). **When testing for INR, you must confirm that the measured result is displayed in INR prior to using the result and whenever the date and time settings are modified.**



The measuring unit is displayed next to the result.

To reset the measuring unit to INR, follow the instructions in the *Testing a Blood Sample* section of the *CoaguChek XS System User Manual for Self-Testing*, version 8.0 and higher or call the Roche Diagnostics Technical Service Center at 1-800-428-4674 for assistance, if the result is displayed in %Q or Sec.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

Before you start testing

If you are new to the CoaguChek XS System, watch the *CoaguChek XS System Patient Training DVD* and read the *CoaguChek XS System Getting Started Guide* and the *CoaguChek XS System User Manual for Self-Testing* before you start testing.

Storing the test strips

Store the test strips in their original container with the cap tightly closed. You can store test strips at room temperature or in the refrigerator (2-30 °C or 36-86 °F). The test strips can be used up until the expiration date printed on the box and test strip container.

Throw the test strips away if they are past the expiration date.

Handling the test strips

When you are ready to test, remove 1 test strip from the container and **immediately close the container. Make sure it seals tightly.**

You must use the test strip within 10 minutes of removing it from the container. Otherwise, you may get an error message and you will have to repeat the test.

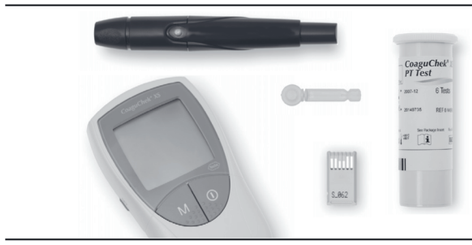
Step 1: Getting ready to test - gather supplies

Materials provided

- Container of CoaguChek XS PT Test strips REF 04625374160
- Test strip code chip

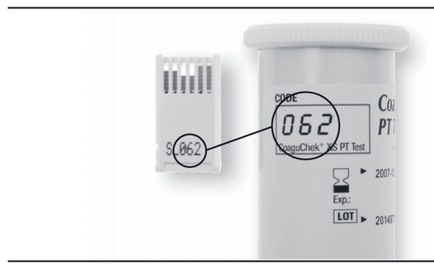
Materials required (but not provided)

- CoaguChek XS Meter
- Lancing device and lancets (Follow the manufacturer's instructions for use.)



Place the meter on a flat surface (like a table or countertop) or hold it roughly horizontal so that it will not vibrate or move during testing. Vibrations or other movement can result in an error message.

If you are using test strips from a new, unopened box, you will need to change the test strip code chip. The 3-number code on the test strip container must match the 3-number code on the code chip. To install the code chip, follow instructions in the *Code Chip* section of the *CoaguChek XS System User Manual for Self-Testing.*



Step 2: Getting a good drop of blood

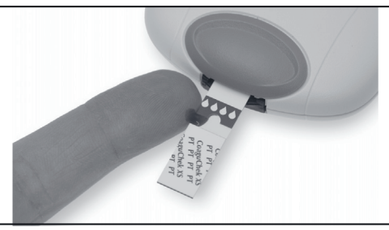
Increasing the blood flow in your finger will help you get a good drop of blood. Before you lance your finger, try the following techniques until you see that your fingertip has good color:

- Warm your hand by holding it under your arm, using a hand warmer, and/or washing your hand with warm water.
- Hold your arm down to the side so that your hand is below your waist.
- Massage your finger from its base.
- If needed, immediately after lancing, gently massage the finger from its base until a drop of blood is formed. Do not press or squeeze the finger.

Step 3: Performing the test

1. Wash your hands with warm, soapy water. **Dry completely.**
2. Remove 1 test strip from the container and **immediately close the container. Make sure it seals tightly.** Do not touch the test strip with wet hands or wet gloves. This may damage the test strips.
3. Insert a test strip as far as you can into the meter. The meter powers ON.
4. Confirm that the number displayed matches the number on the test strip container, then press **M**. If the numbers are different, make sure you are using the code chip that came with the test strips you are using. If they still do not match, call the Roche Diagnostics Technical Service Center at 1-800-428-4674.

5. An hourglass appears as the meter warms up, which takes up to 30 seconds.
6. When the meter is warmed up, a flashing test strip and blood drop symbol appear and the meter begins a countdown. You have 180 seconds to apply blood to the test strip.
7. Use the lancet device to perform a fingerstick. **Set the penetration depth to 5.** See the *CoaguChek XS System User Manual for Self-Testing* for more information. **After sticking your finger, you have 15 seconds to apply blood to the test strip.** If it takes longer to form a good drop of blood, lance a different finger for the test.

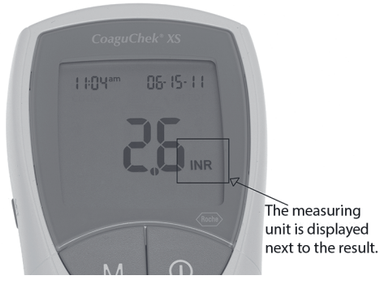


8. Apply 1 drop of blood to the top or side of the target area.

It's important to hold the blood drop to the test strip until you hear a beep.

9. You'll see the hourglass when the blood test begins. Then, pull your finger away from the test strip.
Remember to apply only one drop of blood—don't add more. Do not touch or remove the test strip when a test is in progress.
The result appears in about 1 minute.

Verify that the measuring unit next to the result is INR.



The measuring unit is displayed next to the result.

To reset the measuring unit to INR, follow the instructions in the *Testing a Blood Sample* section of the *CoaguChek XS System User Manual for Self-Testing*, version 8.0 and higher or call the Roche Diagnostics Technical Service Center at 1-800-428-4674 for assistance, if the result is displayed in %Q or Sec.

10. Record the result on the *CoaguChek XS System Prothrombin Time Self-Testing Log Book*. Call your doctor with the test result.
11. Properly dispose of the used lancet and test strip.
12. Power the meter OFF.

If you need to redo a test, use a new lancet, a new test strip, and a different finger.

Limitations of procedure
Information for you and your physician

- The CoaguChek XS System for patient self-testing should not be used for patients being treated with any direct thrombin inhibitors, including Hirudin, Lepirudin, Bivalirudin and Argatroban.
- The CoaguChek XS PT Test for patient self-testing uses only fresh capillary blood from a fingerstick.
- The blood drop must be a minimum of 8 µL in volume. Low sample volume will cause an error message.
- Never add more blood to test strip after test has begun or perform another test using the same fingerstick.
- When a patient is on intravenous infusion therapy, do not collect fingerstick sample from arm receiving the infusion line.
- Hematocrit ranges between 25-55 % do not significantly affect results.
- Testing has confirmed that PT/INR test results are *not* affected by:
  - Ascorbic Acid up to 30 mg/L
  - Bilirubin up to 30 mg/dL
  - Lipemic samples containing up to 500 mg/dL of triglycerides
  - Hemolysis up to 1000 mg/dL
  - Clopidogrel (Plavix®) up to 20 mg/dL
  - Fondaparinux (Arixtra®) up to 0.5 mg/L
  - Heparin concentrations up to 0.8 U/mL
  - Low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL
- Information about pharmacokinetics and the dosage-plasma-relation of the respective heparin are provided in the package insert by the legal manufacturer of the drug.

  INR results from patients treated with Direct Oral Anticoagulants (DOACs) e.g. rivaroxaban, apixaban, edoxaban, betrixaban and dabigatran may be influenced and should be confirmed with an alternative laboratory method.

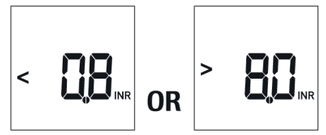
  Note: Samples from patients treated with the following drugs must not be tested with the system: protamine sulfate, oritavancin, calcium dobesilate.
- ⚠ The action of oral anticoagulants (coumarin derivatives) can be increased or weakened when other medication is taken simultaneously (e.g. antibiotics, but also prescription-free medication like pain relievers, antirheumatic medication and medication against influenza). This, in turn, can also lead to either an increase or a decrease in prothrombin time (INR). If other medication is taken, it is recommended that the prothrombin time be checked more frequently and that the anticoagulant dose be subsequently adjusted.
- The presence of anti-phospholipid antibodies (APAs) such as Lupus antibodies (LA) may lead to prolonged clotting times, i.e., they may cause false-high INR values. If you have or suspect that you have APAs, discontinue testing until you discuss with your physician.
- Differences in reagents, instruments, and pre-analytical variables can affect prothrombin time results. These factors should be considered when comparing results from different test methods. Results obtained with the CoaguChek XS System for patient self-testing may not consistently correlate with clinical laboratory results, particularly for certain types of laboratory reagents. Your doctor can provide additional information regarding results comparison.

Drug interferences are measured based on recommendations given in CLSI guidelines EP07 and EP37 and other published literature. Effects of concentrations exceeding these recommendations have not been characterized.

Very low or very high test results

The CoaguChek XS PT Test strips provide test results in the range of 0.8 to 8.0 if the result unit is set to INR.

If the meter displays < (less than) **0.8** or > (greater than) **8.0**, confirm that the measuring unit is set to INR. To reset the measuring unit to INR, follow the instructions in the *Testing a Blood Sample* section of the *CoaguChek XS System User Manual for Self-Testing*, version 8.0 and higher or call the Roche Diagnostics Technical Service Center at 1-800-428-4674 for assistance, if the result is displayed in %Q or Sec. If the measuring unit is set correctly to INR, repeat the test. If, when you repeat the test, you get the same display (either < **0.8** or > **8.0**), call your doctor.



Possible causes of errors and error messages

If problems occur during testing, please check the following:

- The blood drop must be a minimum of 8 µL in volume. Low sample volume will cause an error message.

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- Are you testing exactly as described in the according meter manual and also in "Step 2: Getting a good drop of blood" section in this document? Please read the instructions carefully.
- Always make sure the test strips are correctly stored (see section "Storing the test strips") and that you carry out the test within 10 minutes of removing a test strip from its container.
- Please check date and time on the meter display. Incorrect settings might cause an error message.
- Is the test strip guide dirty? Clean the meter as described in the meter manual. Repeat the test with a new test strip.

⚠ Certain errors might occur sporadically due to an activation of the system fail safe mechanisms that are designed to prevent the release of wrong measurement results. In rare cases, these errors might also be received by patients under clinical conditions, e.g. treatment with vitamin K antagonists in combination with antibiotics and/or chemotherapeutics, or if the blood sample contains extremely high concentrations of oxidizing substances, e.g. after a vitamin C infusion. Also, in rare cases, patients with abnormal or unusually long clotting times may receive "error 6" or "error 7" messages.

ⓘ **Repeat test with a new strip. If "error 6" or "error 7" messages display repeatedly, you must use an alternative test method to confirm the result. Please contact your physician without delay.**

If the meter displays any other error message, refer to the *Error Messages* section of the *CoaguChek XS System User Manual for Self-Testing.*

Built-in controls

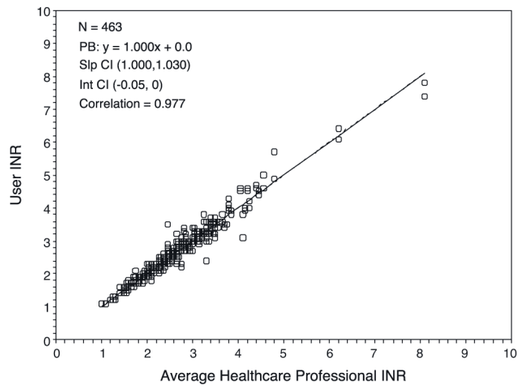
The CoaguChek XS System has built-in quality control functions in the meter and test strips. The meter automatically runs its own quality control test as part of every blood test, so you never have to run quality control tests with liquid quality control solutions. For more information about the built-in quality control functions, see the *CoaguChek XS System User Manual for Self-Testing.*

Performance Characteristics

Measuring range: The CoaguChek XS PT System has a measuring range of 0.8-8.0 if the unit result is set to INR.

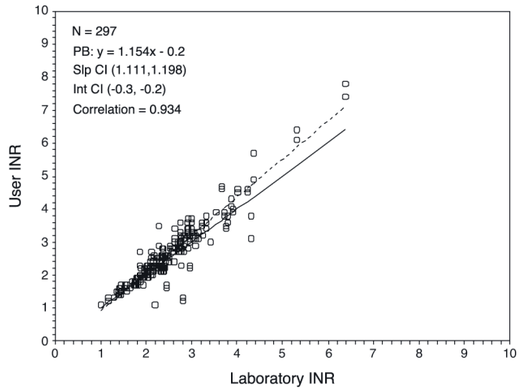
Accuracy: A study was conducted comparing test results obtained by trained users with those obtained by healthcare professionals, when both were using the CoaguChek XS System. The correlation was very good, as indicated by the following statistics: N=463, Slope=1.000, Intercept=0.0 and Correlation Coefficient=0.977. This study shows that trained users are able to obtain results that are as accurate as those obtained by healthcare professionals trained in the use of the CoaguChek XS System.

Results Comparison: User vs Healthcare Professional



The test results obtained by trained users were also compared to results obtained using a laboratory-based reference method. Results are shown in the following plot.

Results Comparison: User vs Laboratory Result



Study user demographics: A clinical study was conducted by Roche Diagnostics, consisting of four visits to the clinical site. Informed consent and randomization occurred at Visit 1. Testing began at Visit 2. Ninety-one patients completed at least one visit after Visit 1. The following table outlines the demographic information for the trained users who completed at least one visit after Visit 1.

Demographic	Number	Percent
Total number of users	91	100%
Caregivers	4	4.4%
Males	51	56%
Females	40	44%
Age range (years)	32-89	N/A
Mean age (years)	64	N/A
Age 65 – 69 years	16	17.6%
Age 70 – 74 years	13	14.3%
Age 75 years and up	16	17.6%
Education level- eighth grade or less through advanced college degree	91	100%
Median education level	Some college	N/A
On warfarin 3 – 12 months	19	20.9%
On warfarin 1 – 2 years	22	24.2%
On warfarin 3 – 5 years	23	25.3%
On warfarin > 5 years	27	29.7%
Atrial fibrillation	38	41.8%
Valve replacement	25	27.5%
Stroke/stroke prevention	7	7.7%
DVT	5	5.5%
Other heart conditions	6	6.6%
Other clotting disorders	10	11%

There were 107 patients enrolled. A total of 88 patients completed all four visits to the site. The reasons for drop-outs were as follows:

Reason for Drop-Out	# of Subjects
Felt it was too stressful	2
Didn't have time	3
Didn't want to use meter on his own	1
Didn't think he could learn to use meter	1
Was having knee surgery	1
Study terminated prior to Visit 4	1
Unknown	7
Disqualified due to target INR range outside of study protocol	3

Precision: A study was conducted and the precision of duplicates for capillary blood results was calculated for both trained users and healthcare professionals. The following results were obtained:

	User Results	Professional Results
N	214	249
Mean, INR	2.57	2.52
SD	0.13	0.13
CV, %	5.13	5.36

This study shows that trained users are able to obtain results that are as precise as those obtained by healthcare professionals trained in the use of the CoaguChek XS System.

Note for the physician:

Note: While the INR unit was created in general for the best possible comparison between methods (Point-of-Care vs. laboratory methods and between laboratory methods), several factors can have a significant or even systematic influence on the comparison of PT/INR results obtained with different methods. The most important factor, when changing methods, is the type of thromboplastin used (i.e. human recombinant, rabbit or bovine).[1]

The CoaguChek method uses human recombinant thromboplastin. Therefore, the comparability to tests using other human recombinant thromboplastins is best, whereas higher deviations can occur with other thromboplastin types.

However, those higher differences between thromboplastins of different (rabbit, bovine) origin are not an issue specific for CoaguChek assays. Similar differences can be observed when a human recombinant thromboplastin-based laboratory method is compared with several other (rabbit, bovine) laboratory methods. To minimize these differences, in a monitoring situation, it is recommended that each laboratory uses results from a method using only one type of thromboplastin for each patient.

If testing methods for the comparison of patient INR values are changed, especially when methods with thromboplastins of a different origin are used, the deviations which may occur need to be taken into account.

Other potential influencing factors:

- Variations between different laboratory instruments and between different reagent lots
- Pre-analytics, i.e. sample tubes of different manufacturers used for laboratory testing

Additional Information

The *CoaguChek XS System User Manual for Self-Testing* contains more information. If you need technical help, call the Roche Diagnostics Technical Service Center at 1-800-428-4674.

References

1 Plesch W, Wolf T, Breitenbeck N et al. Results of the performance verification of the CoaguChek XS System. Thromb Res 2008;123:381-389.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

REF	Catalogue number
LOT	Batch code
IVD	In vitro diagnostic medical device
	Manufacturer
	Contains sufficient for <n> tests
	Use-by date
	Temperature limit
	Consult instructions for use
SYSTEM	Analyzers/Instruments on which reagents can be used
GTIN	Global Trade Item Number
	Please pay attention to the code chip in the test strip box

LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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