CoaguChek XS PT Test

REF	Σ	SYSTEM
07797826160	24	CoaguChek® XS
04625315160	2 x 24	

This insert is for healthcare professional use. These test strips are to be used with the CoaguChek XS System. This is a CLIA Waived test system. A Certificate of CLIA Waiver (or higher) is required to perform the test. Information on obtaining CLIA certificates can be found at www.cms.hhs.gov/clia. Facilities performing testing must have a CLIA Certificate of Waiver. 42 USC 263a(c)(2).
Any modifications and/or failure to follow test system instructions, including those for limitations/intended use and performance of QC testing as a failure alert mechanism, results in use that is considered high complexity and subject to all applicable CLIA requirements. All applicable state and local laws must be met. Laboratories with a certificate of waiver must follow the manufacturer's instructions for performing a test. 42 CFR 493.15 (e) (1).

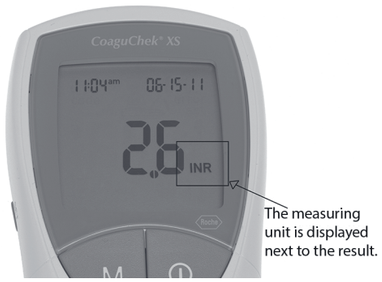
Purpose

The CoaguChek XS System is intended for use by professional healthcare providers for quantitative prothrombin time testing for monitoring warfarin therapy. The CoaguChek XS System uses fresh capillary or nonanticoagulated venous whole blood.

Caution: For in vitro diagnostic use.

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 (Sec) and % Quick (%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.



To reset the measuring unit to INR, follow the instructions in the *Advanced Features* section of the *CoaguChek XS System User Manual*, version 9.0 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 Training DVD* and read the *CoaguChek XS System User Manual* and *Getting Started Guide* before testing.

Storing the test strips

Store the test strips in their original container, with the cap tightly closed. You can store the 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.

Discard the test strips if they are past the expiration date on the container.

Handling the test strips

Only use the CoaguChek XS PT Test strips with the CoaguChek XS meter.

When you are ready to test, remove 1 test strip from the container. Do not touch the test strip with wet hands or wet gloves. This may damage the test strips. **Close the container 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.

Sample collection and preparation

The steps that follow apply to collecting a blood sample from a fingerstick. Optionally, you may use a non-anticoagulated plastic capillary tube to collect the fingerstick blood sample. You may also use the CoaguChek XS System to test venous blood. See *Optional Testing Methods* in the *CoaguChek XS System User Manual* for more information. When collecting any type of sample, follow universal blood collection precautions and guidelines.

Step 1: Getting ready to test - gather supplies

Materials provided

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

Materials required (but not provided)

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

If you have opened a new box of CoaguChek XS PT Test strips, you must replace the old code chip in the meter with the one included in the new box. When a test strip lot is used for the first time, the meter requests the corresponding code chip. If test strip lot and code chip do not correspond, an error message is displayed and a measurement is not possible. To install the code chip, follow the instructions in the *Code Chip* section of the *CoaguChek XS System User Manual*.

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.

Step 2: Getting a good drop of blood

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

- Warm the hand by having the patient hold it under his or her arm, use a hand warmer, and/or wash the hand with warm water.
- Have the patient hold his or her arm down to the side, so that the hand is below the waist.
- Massage the 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 the patient's hands with warm, soapy water or wipe the finger with alcohol. Allow the patient's finger to dry completely before performing the fingerstick.
2. Take a test strip out of the container. **Close the container tightly.**
3. Insert the test strip as far as you can. 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.
5. An hourglass flashes as the meter warms the test strip, which takes up to 30 seconds.
6. When the test strip is warmed, 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 to perform a fingerstick.
8. Apply 1 drop of blood to the top or side of the target area. **You must apply blood to the test strip within 15 seconds of lancing the finger** and within 30 seconds when using venous blood. Applying blood later than that may produce an inaccurate result as the coagulation process will have begun.
9. Do not add more blood. Do not touch or remove the test strip when a test is in progress. The flashing blood drop symbol changes to an hourglass symbol when the meter detects sufficient sample. If the meter's beeper is turned on, a beep sounds as well.
10. The result appears in about 1 minute.

    Verify that the measuring unit next to the result is INR.
    To reset the measuring unit to INR, follow the instructions in the *Advanced Features* section of the *CoaguChek XS System User Manual*, version 9.0 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.

    Record the result.
11. Properly dispose of the used lancet and test strip.
12. Power the meter OFF.

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

Technical information

How the test works

The CoaguChek XS PT Test, used as directed with the CoaguChek XS Meter, will provide an electrochemical measurement of prothrombin time following activation of blood coagulation with human recombinant thromboplastin. In simple terms, blood works with the chemicals in the test strip to produce a small electric current in the test strip that measures blood-clotting time.

Contents of the test strip

The test strip contains reagent (human recombinant thromboplastin), as well as stabilizers and preservatives.

Limitations of procedure

- The CoaguChek XS System should not be used for patients being treated with any direct thrombin inhibitors, including Hirudin, Lepirudin, Bivalirudin and Argatroban.
- 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.
- The CoaguChek XS PT Test uses only fresh capillary or non-anticoagulated venous whole blood. Plasma or serum cannot be used.
- Use only plastic syringes without anticoagulants or additives. Glass tubes or syringes must not be used.
- 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 the test strip after the test has begun or perform another test using the same fingerstick.
- When a patient is on intravenous infusion therapy, do not collect sample from the arm receiving the infusion line.
- Hematocrit ranges between 25-55 % do not significantly affect test results.
- Testing performed with the following in vitro spiked samples or native blood samples (for testing of triglycerides) indicated no significant effect on test results:

  - 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
  - Heparin concentrations up to 0.8 U/mL
  - Low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL
  - Clopidogrel up to 20 mg/dL
  - Fondaparinux (Arixtra®) up to 0.5 mg/L

NOTE: Samples from patients treated with the following drugs must not be tested with this 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). Additional medication should only be taken if prescribed by the treating physician. If other medication is taken, it is recommended that the prothrombin time be checked more frequently and that the anticoagulant dose be subsequently adjusted as directed by the treating physician.

Anti-phospholipid antibodies (APA) like Lupus antibodies (LA) may falsely prolong coagulation times, i.e. they may cause false-high INR values and false-low Quick values. Where APA are known to be present, a result should be obtained using an APA insensitive laboratory method.[1]

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.

Error messages

Errors displayed on the meter are generally due to an activation of the system fail safe mechanisms which are designed to prevent the release of wrong measurement results.

Special attention is required if the following errors occur:	
"error 6" **"error 7"**	In rare cases, these errors may also be received for patients under clinical conditions which can lead to abnormal or unusually long clotting times (> 10 INR, < 5 % Quick). This can happen during treatment with vitamin K antagonists in combination with antibiotics, and/or chemotherapeutics, or extremely high concentrations of oxidizing substances. Additionally, in rare cases, patients with abnormal or unusually long clotting times may receive these error messages. If one of these errors appears again after the test is repeated, check the result using another method. Please inform the patient to seek immediate medical attention.

Expected results

The CoaguChek XS Meter displays test results in units equivalent to laboratory plasma measurements. Results may be displayed in the International Normalized Ratio (INR=(PT/Mean Normal PT) ^{ISI}), seconds (Sec), and % Quick (%Q) (a unit used mainly by healthcare professionals in Europe).

Each lot of test strips is calibrated to a reference lot that is traceable to the WHO International Reference Preparations. Normal INR levels vary from person to person. When the CoaguChek XS PT Test was performed using the CoaguChek XS Meter on 121 normal, healthy, warfarin-free individuals using venous and capillary samples, 97 % of the INRs ranged from 0.9 to 1.1. For the purpose of providing universal INR results, the Mean Normal Prothrombin Time (MNPT) has been established as 12 seconds for healthy volunteers and the International Sensitivity Index (ISI) for the system has been established as 1.

The physician must determine the best INR level depending on the reason for anticoagulant treatment and how each individual responds to treatment (based on Prothrombin Time). Each physician should establish expected values for his or her patient population or individual patients.

Differences in reagents, instruments, and pre-analytical variables can affect prothrombin time results. These factors should be considered when comparing different prothrombin time test methods.[2] Experience comparing results obtained using the CoaguChek XS System to those obtained using common clinical laboratory reagents shows that the CoaguChek XS System correlates well with the following clinical laboratory reagent: Dade Innovin. Other clinical laboratory reagents may not consistently correlate with the CoaguChek XS System.

Unusual results

If the meter displays an error message, refer to the *Error Messages* section of the *CoaguChek XS System User Manual*, version 9.0 and higher. If the meter displays an unusual test result (other than an error message), check the following items:

- Is the correct code chip in the meter? The 3-number code on the test strip container must match the 3-number code on the code chip.
- Is the meter set up with the correct date and time?
- Is the meter set up with the correct measuring unit of INR?
  To reset the measuring unit to INR, follow the instructions in the *Advanced Features* section of the *CoaguChek XS System User Manual*, version 9.0 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.

Certain drugs may affect results by affecting warfarin pharmacology. The potential effect of a drug interaction with warfarin or the effect of underlying diseases (e.g., liver disease, congestive heart failure) must be considered when interpreting a result.
Also, changes in the patient's diet can cause unusually low or high results.

Any unusual result should always be followed up with appropriate coagulation studies and inquiries to define the cause of the unusual result. If the result does not match the clinical symptoms, repeat the patient test to rule out procedural error.

Performance characteristics

Measuring range: The CoaguChek XS System has a reportable range of 0.8 to 8.0 INR.

Sensitivity: The CoaguChek XS PT Test is sensitive to various clotting factors as determined by in vitro tests. Single factor depleted plasma was combined with a normal plasma pool to produce a series of diluted plasma samples. These plasma samples were then tested using three representative lots of the CoaguChek XS PT Test across 16 CoaguChek XS meters. The results, as seen in the graph below, represent the typical CoaguChek XS PT Test sensitivity to Factors II, V, VII, and X.

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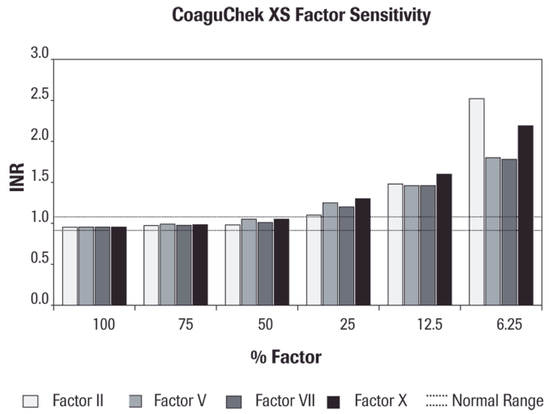
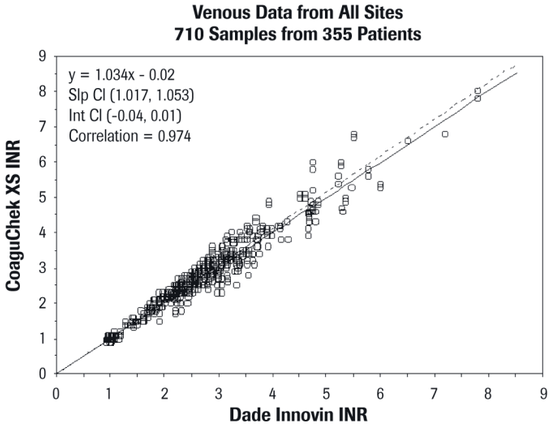


Expected waiver performance

Accuracy: 710 venous samples were collected from 355 outpatients at three external sites. The INR of each sample was compared to the INR of a venous plasma sample measured on a Dade Sysmex 560 Analyzer using Dade Innovin (ISI = 1.02). The patient clinical conditions included (number of patients): normal - not on warfarin (62), atrial fibrillation (174), valve replacement (35), stroke/TIA (28), DVT (16), other heart-related disorders (4), other clotting disorders (6), other (30).

Venous Data:

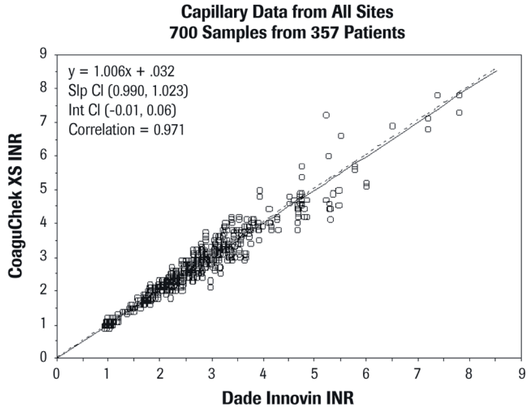
	N	Slope	Intercept	Correlation
Site 1	232	1.129	-0.10	0.983
Site 2	230	1.111	-0.11	0.971
Site 3	248	0.984	-0.03	0.986
All	710	1.034	-0.02	0.974



Accuracy: 700 capillary samples were collected from 357 outpatients at three external sites. Capillary blood samples were assayed on the CoaguChek XS meter with the CoaguChek XS PT Test and venous plasma samples were measured on a Dade Sysmex 560 Analyzer using Dade Innovin (ISI = 1.02) The results comparison is as follows:

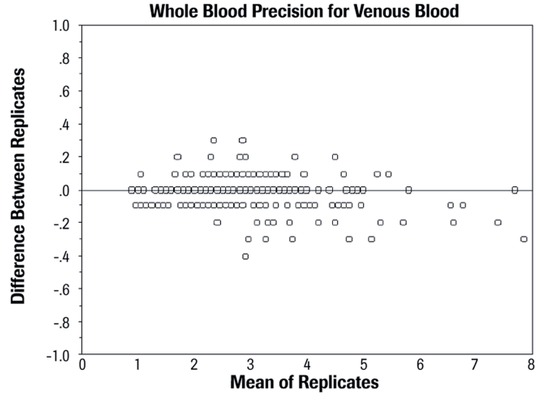
Capillary Data:

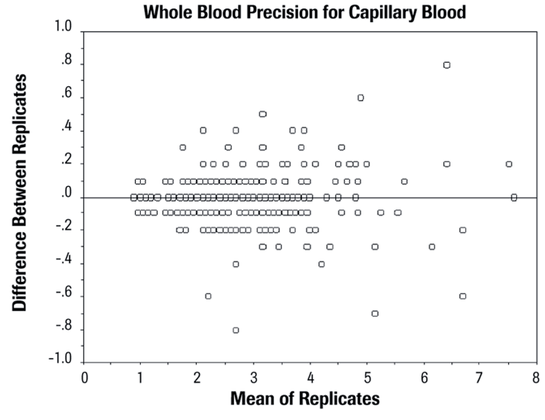
	N	Slope	Intercept	Correlation
Site 1	230	1.111	-0.10	0.973
Site 2	229	1.081	-0.068	0.979
Site 3	241	0.952	0.02	0.985
All	700	1.006	0.032	0.971



Precision: Whole blood precision was determined for venous and capillary blood from sample duplicates collected at three sites. The following charts represent whole blood precision for venous and capillary blood.

Sample	N	Mean INR	SD	CV, %
Venous	357	2.59	0.06	2.42
Capillary	344	2.59	0.11	4.35





Note: The INR was introduced to normalize changes in PT reagents in order to correct for variation between laboratory methods. In general, several factors can have a systematic influence on the comparison of PT/INR results obtained with different methods. Most importantly, when changing testing methods, the type of thromboplastin used (i.e., human recombinant or rabbit) should be considered.

The CoaguChek system uses human recombinant thromboplastin. Therefore, the comparability to other human recombinant thromboplastins is best, whereas deviations can occur when compared to methods using other thromboplastins. However, those deviations between thromboplastins of different origin (e.g., rabbit based) are not specific to CoaguChek products. Similar differences can be observed when a human recombinant thromboplasin-based laboratory method is compared to other laboratory methods. The CoaguChek XS System correlates well with the following clinical laboratory reagent: Dade Innovin.

To minimize these differences, in a monitoring situation, it is recommended that each site uses results from one type of thromboplastin method 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 as a result need to be taken into account.

Other potential influencing factors may include but are not limited to:

- Laboratory method end point detection
- Reagent lot-to-lot variations
- Pre-analytics (e.g., sample tubes of different manufacturers used for laboratory testing)

Built-in controls and diagnostics

The CoaguChek XS System has quality control functions integrated into the meter and test strips, so you do not have to run quality control tests with liquid quality controls. The meter automatically runs its own quality control test as part of every blood test. For more information about the built-in quality control functions, see the *CoaguChek XS System User Manual*.

Additional information

The *CoaguChek XS System User Manual* contains more information. If you still have questions, call Roche Diagnostics Technical Service Center at 1-800-428-4674.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to FDA's Med Watch 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).

Return policy

If there is a problem with the CoaguChek XS PT Test Strips, you may be asked to return them, along with the test strip code chip, to Roche Diagnostics. Before returning, call Roche Diagnostics Technical Service Center at 1-800-428-4674. You will be mailed a return authorization label which must be placed on the shipping carton.

References

1 Moll S and Ortel TL Monitoring Warfarin Therapy in Patients with Lupus Anticoagulants. Annals of Internal Medicine 1997;127:177-185.

2 Loeliger EA, van den Besselaar AMHP, Lewis SM. Reliability and Clinical Impact of the Normalization of the Prothrombin Times in Oral Anticoagulant Control. Thromb Haemostas. 1985;53:148-154.

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):

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume for reconstitution
GTIN	Global Trade Item Number
	Please pay attention to the code chip in the test strip box

FOR US CUSTOMERS ONLY: 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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