

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. Any modifications and/or failure to follow test system instructions, including those for limitations/intended use and performance of QC testing as a fail-ure alert mechanism, results in use that is considered high complexity and subject to all applicable CLIA requirements.

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.

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 to 30 °C or 36 to 86 °F). When stored properly, the test strips can be used until the expiration date printed on the test strip container. Discard the test strips if they are past the expiration date on the container.

Handling the Test Strips

When you are ready to test, remove 1 test strip from the container. Do not open a container of test strips or touch a 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 nonanticoagulated 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:
- CoaguChek XS Meter
 - CoaguChek XS PT Test Strip
 - Test Strip Code Chip
 - CoaguChek Lancet [REF] 04348150001 (Follow the manufacturer’s instructions for use.)

If you are using test strips from a new, unopened box, you must 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 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 squeeze the finger from its base to encourage blood flow.

Step 3: Performing the Test

- 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.
 - Take a test strip out of the container. **Close the container tightly.**
 - Insert test strip as far as you can. The meter powers ON.
 - 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.
 - An hourglass flashes as the meter warms the test strip, which takes about 30 seconds.
 - 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.
 - Use the lancet to perform a fingerstick.
 - 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.**
 - 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.
 - The result appears in about 1 minute. Record the result.
 - Properly dispose of the used lancet and test strip.
 - 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 1.5 U), as well as stabilizers, preservatives, and additives.

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.
- The CoaguChek XS PT Test uses only fresh capillary or nonanticoagulated 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 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 sample from 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 (triglycerides) indicated no significant effect on test results:
 - 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 up to 5 mg/L
- The presence of anti-phospholipid antibodies (APAs) such as Lupus anti-bodies (LA) can potentially lead to prolonged clotting times, i.e., elevated INR values. A comparison to an APA-insensitive laboratory method is recommended if the presence of APAs is known or suspected.'
- In rare cases, patients with long clotting times (> 8 INR) may receive an “ERROR 7” message on the meter display. If this error message appears again when the test is repeated, the result must be checked using another method.

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, and % Quick (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 reagents: Dade Innovin, Ortho Recomboplastin, and Dade Thromboplastin C+. 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*. 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?

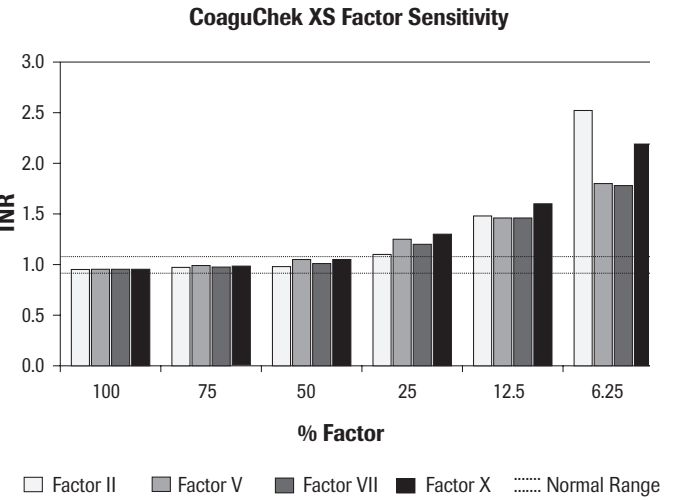
Certain drugs may affect results by affecting warfarin pharmacology. The potential effect of a drug interaction with warfarin or the effect of underlying diseases (e.g., liver disease, congestive heart failure) must be considered when interpreting a result.

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.

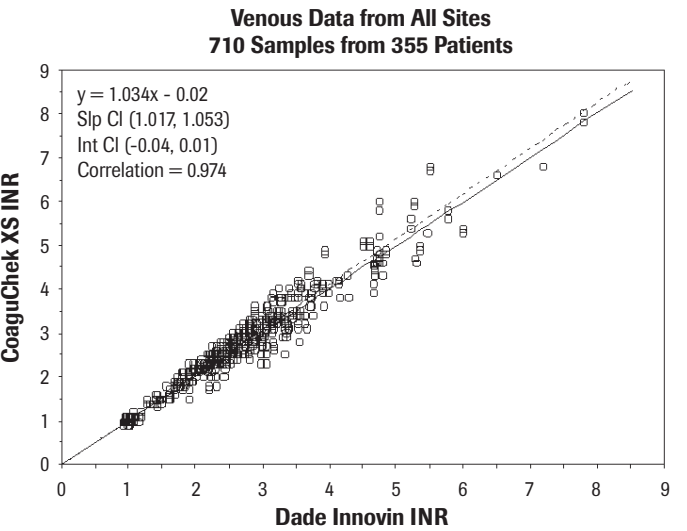
Sensitivity: The CoaguChek XS PT Test is sensitive to various clotting factors as determined by *in vitro* tests. Single factor depleted plasma was combined with a normal plasma pool to produce a series of diluted plasma samples. These plasma samples were then tested using three representative lots of 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.



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).

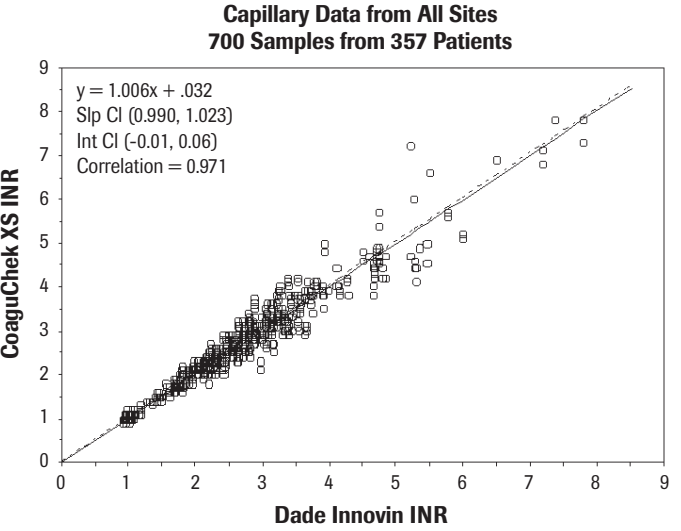
Venous Data:				
	N	Slope	Intercept	Correlation
Site 1	232	1.129	-0.10	0.983
Site 2	230	1.111	-0.11	0.971
Site 3	248	0.984	-0.03	0.986
All	710	1.034	-0.02	0.974



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:

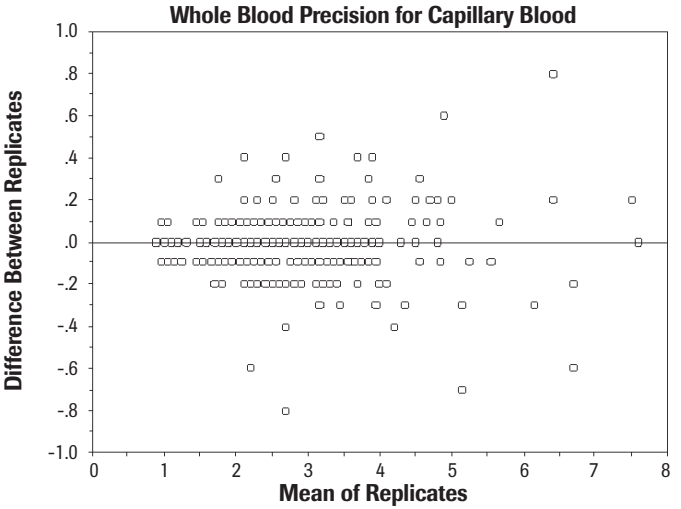
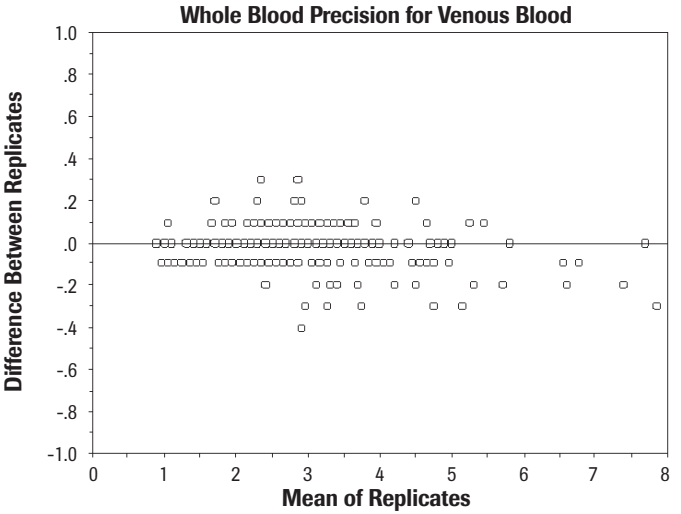
Capillary Data:

	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



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*.

References

- Moll S, Ortel TL, Metering Warfarin Therapy in Patients with Lupus Anti-coagulants. Annals of Internal Medicine. 1997;127:177-185.
- 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.

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.

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, 24 hours a day, 7 days a week, 365 days a year.

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

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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